Kim Bateman
(kbateman@healthinsight.org)

Please consider this my formal input that the guideline should specifically recommend sleep studies for any patient with suspected obstructive sleep apnea syndrome and for patients receiving > 50 mg methadone a day or 100 mg morphine equivalent to square with the recommendations the outreach team is making for safety. We are also recommending an EKG to look for QT prolongation in methadone patients reaching that daily dosage.

I understand that there is no empiric proof that these actions will reduce death. They are based on expert opinion and the observations that almost all deaths are due either to cardiac or respiratory arrest, that QT prolongation occurs with methadone and increases with dose and with other medications that prolong QT, and that all forms of respiratory depression (hypopnea, obstructive sleep apnea, and central sleep apnea) increase in likelihood as opioid doses increase. This should be stated in the guideline. I plan to contact Lynn Webster, (whose expert opinion influences these recommendations) for his additional input.

I've attached the current slideset to illustrate our reasoning for these recommendations further. Please also pay attention to the slides at the end (attached separately) describing the guidelines. I'd like your input on whether they accurately represent the guidelines as you understand them, and anticipate they will look in the final version.

Thanks. Kim

Anonymous

Have the members of the guidelines committee truly accurately disclosed their financial interest in pursing rules that allow the free flow of narocits? Does anyone on the committee have a medical practice that would financially benefit by NOT having more restrictions on narcotic prescribing and has that been disclosed?

Anonymous

Before prescribing these strong medications to a patient who may have to bear the burden of addiction for the rest of their life, I think the doctor should have to have a consultation for the patient with another doctor who can objectively determine if this patient should be given these strong medicines, probably for life. They should also have detailed counseling on the effects, addictive potential and the liklihood that ever increasing doses will be needed and death can result along with loss of social, sexual, and occupational functioning.

John Barbuto
doctorbarbuto@comcast.net

Hi Erin,May I suggest the definition of "function" as given on page 7 is not adequate. That particular definition, while claiming to be "broad", assesses function only in terms of soft psychological parameters. Later, such as on page 16, the Guidelines do advocate solid criteria for assessment of function - with true reference to social capacity. So, some of the strength of the latter definitions of function needs to be brought up to the "short version" on page 7. For example, the definition of function in the footnote could be expanded to include"...defined broadly to include emotional, cognitive and psychological function as well as measurable physical and social capacity."

Robert F. Finnegan, MD, DABPM
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I did not want to post for public comment... you have the threshold for consultation (page 64 toward the end) for morphine as 120 MG but for hydrocodone as 30 mg.The two drugs are equipotent and I would suggest hydrocodone be 120 mg as well. I will be part of a team presenting the HealthInsight program to the Salt Lake County Medical Society tomorrow night and would talk about these then.

Thanks,

Jaynie Brown
jayniebrown@gmail.com

I believe that it is vitally important that , in prescribing opiods for pain, that doctors warn the patient that there is a risk for becoming dependant or additcted to the medication, and give them the physical and emotional signs to look for and beware of. The doctor should advise the patient to discontinue use and contact him or her for a substitute pain medication. To do less than that is criminal. Doctors should also ask the patient who has been on the meds at their next visit or conversation if the patient has noticed any symptoms, explaining that the sooner the dependancy is discovered the better the addiction treatment results. Some may argue that this will discourage people from taking the pain meds; but most of us a pain-wimps anyway and won't let that deter us from seeking the relief we need.

Anonymous

The draft guideline is very worrisome becuase as I read it from a perspective of a nurse practitioner or GP in a small town, it doesnt provide me any specific guideline on how to treat certain chronic pain conditions and it certainly doesn't point out the fact that there is virtually no good epidemiological evidence to support the use of chronic narcotics for non cancer pain. As a result, this guideline appears to take what is already a massive and deadly prescribing problem in utah and validates it by allowing for practitioners to continue the same practices of prescribing as long as a few steps are taken. For heaven sakes, it doesn't even preclude the use of chronic high dose narcotics in known drug abusers it just suggests the practitioner consider this issue. This guideline really doesn't solve the problem and has a potential to make it much worse by legitimizing current prescribing practices as long as a few t's are crossed. This needs strong language stating that such prescribing hasn't been shown to be effective, kills and disabled people and ruins families, lives and communities. This needs strong restrictions on the use of these medications for non cancer pain. Please don't publish this guideline as is; more people will die needlessly.

Anonymous

Please make the guideline more clear in warning patients and doctors that prescribing these medications is usually a marriage for life. The medications alter lives and families forever and the relationship is usually "until death does us part". Unfortunately, death comes too soon for many who are assaulted by these prescribing practices.

Michael Marble, LSAC
mvmarble@comcast.net

I'm very interested in the overall direction you are taking regarding the task of deciding so many important issues. I spend eight hours per day dealing with the SA side of opiates (Methadone and Suboxone). I see people who want to get and keep control in their lives. Keep up the good work!

Dr Ross Poore
doctorpens@aol.com

I have a cousin that takes a significant amount of prescription pain medications. My major concern is that I see little base line analysis to see if he can function with a lower dose of medication. Related to this is his driving. He takes 4 oxycotin daily, oxycodone, and at least one additional pain medication for "break through" pain. He can not sit in a chair and carry on a conversation without nodding. There needs to be a standard that Dr.'s need to notifiy the Department of Public Safety when prescription doses reach a level that makes it dangerous to drive a motor vehicle. While I care about him he should not be driving. He will not stop driving. There needs to be a procedure that does not require self-disclosure only. Individuals with diabetes, seizures, etc. need a medical review each year. Those are high doses of medications that impact driving should have it reported and there ability to operate a motor vehicle controlled. Thanks for the opportunity to comment.

Erica Kardelis
ekardelis@preciscom.net

I would like to see the state offer a "Buy Back" program for pain medication or other meds that are known to be stolen and used illegally. Instead of telling people to throw away their unused meds, have them take them back to the pharmacy. The pharmacy can pay them per pill, say $1 or even $5, as an incentive to get the meds out of medicine cabinets where they can fall into the wrong hands. Not only would the leftovers not be taken illegally, the pharmacy would now know to cancel any refills left on the prescription.

Bretton Newman, MD
sednadog@comcast.net

i am a hospice medical director, board certified in family medicine and hospice and palliative medicine please note that it would not be practical to order a sleep study or ekg prior to prescribing opioids in hospice patients, also note that the goal of pain management in hospice care is to provide comfort for the patient....these patients have a terminal illness and may be in the process of dying due to disease during opioid titration. i want to be sure that it remains standard of care to be able to provide opioids for hospice patients with the goal of comfort without any type of requirement for sleep studies, ekg's, or other impractical requirements for patients on hospice thank you, brett

Jonas Munger
jmunger73@aol.com

No comments were included.

R Scott Poppen
rsp_44@msn.com

Extend the comment period to December 31.. The significance of these quidelines has just hit the radar screen of most physician weekin the last one week..

Todd Wilcox
trwilcox@wellcon.net

As a physician who treats many chronic pain patients, I am pleased to see some guidelines developed and some additional educational materials available. I work in a correctional setting and so we see large volumes of patients and really have a good sense for what is happening in the community. Most of the docs in town do a pretty good job and are trying hard to be responsible--I rarely have problems with patients managed by them. The one area that is totally missing in these guidelines and represents a major dilemma for me as a physician is what to do with the patients who get treated via the methadone substance abuse clinics. They get put on astronomical doses of methadone and then it falls to me to manage this mess. I rarely see patients on less than 100 mg q day and my personal high from the methadone clinics is 640 mg q day. If you are looking to solve the methadone death problem, you have to tackle the practices at the methadone clinics because that is where patients are being put on dosages that are toxic and they are poorly managed with respect to co-occurring usage of other opiates as well as other medications and substances. I think guidelines are fine and i'm happy to follow them on appropriate patients, but I do struggle with the implementation of the guidelines when you have an unregulated out-of-control methadone source in the community that I then have to clean up after. In my cleanup of those patients, none of these guidelines pertain, the dosages are all multiples of what you recommend, and safe, appropriate medical practice to salvage these patients and detoxify them doesn't correlate with your recommendations in any way. I won't go on, but I have tons of examples of this huge disconnect, call me if you want more info.

Katie Carlson, MD
katiecarlson801@gmail.com

-require a 2nd opinion patient consultation when treatment shifts from acute to chronic

-require a 2nd opinion patient consultation when the dose exceeds a certain level (based on morphine equivalents).

Jeff B. Chung, MD
jchung3729@yahoo.com

I have been treating chronic pain in Utah since 1993. During that time period I have routinely prescribed narcotics to my chronic pain patients. I have had one patient who overdosed on Avinza in 15 years of practice. It appears that this was a purposeful suicide instead of an accidental overdose. I recommend that guidelines be established regarding a likely maximum safe dose of different brands/types of opiates for the use in non malignant chronic pain. Obviously the dangers associated with opiate use increases with the dose. Numerous published studies have reasonably established that the maximum benefit that can be achieved with high dose narcotics is a 30% decrease in chronic pain. At some point the benefit risk ratio of high dose narcotics must tilt to a point where high dose narcotics are more dangerous than helpful. It's all well and good to advise health care professionals to be careful when prescribing narcotics but it would be much more useful for most clinicians to have a more distinct end point where there is a concensus that the dosage of the narcotic/narctotics is high enough to be dangerous and at a point where the risks out weigh the benefits

Tim Houden
timhouden@aol.com
801-387-2090

Thank you!!!! I just received this and at first glance it looks great. I have practiced in the "PAIN' specialty for 15 years and I believe we need more functional restoration programs (multi-specialty) and Less "Pain Clinics"...Let me Know if I can be of any assistance

Mark Anderson
marcux666@yahoo.com

3.2 Immunioassy misses most synthetic opiates and is not in accordance with Utah Law which I believe requires GC/MS confirmation. 5.4 I consistently get letters from pain management physicians stating the patient is safe to drive semis etc. They don't know federal law. I am concerned about what was involved in the "conflict of interest" declaration. Some have direct financial connections to opiate manufactures.

Tim Grange, MD
tsgrange1@msn.com

I just found out about the comment period for the Utah guidelines tonight, Nov 30, after the comment period was over! Please add me to your email list. I'm glad to help -- how can I be of service? Thx

Michael Wren, MD
mwhosp@yahoo.com

Having treated multiple unintentional methadone OD's, I would suggest that additional cautions are in order, including: 1. avoid in patients over say 50 , 2. avoid in patients taking diuretics, 3. warn the patient to avoid rapid self titration down and especially back up.

Recently assumed care of another patient with accidental methadone OD. Also had been on diuretic. Physicians seem not widely aware of that interaction.

Paul Lane, MD
splane5@msn.com

As an emergency physician in one of the busiest ERs in the state this subject is of great concern to me and my coworkers. I have recently written a protocol for our ER with regards to narcotic use in recurrent and chronic pain patients which has had a very beneficial impact on drug seeking behavior in our patients. Having practiced here for over 15 years I can make some recommendations that, I feel, would be of benefit with this problem. 1-The DOPL prescription drug report needs to be more up to date. Real time presciption filling histroy is needed. A national database would also be nice. 2-All pharmacies, if not already required, should be required to participate. 3-Patients should be required to show ID, not only at the pharmacy, but also to the prescriber. 4-Review prescribing habits of physicians. Obviously a pain clinic would be an outlier, but valuable information can be had from others prescribing habits. In my area it appears that a handful of prescribers are generating most of the problems. 5-Ask those caught doctor shopping who they get their drugs from. Surely they must be a valuable resource in identifying problem prescribers 6-I use the DOPL web site frequently, however the login is unnecessarily difficult. Is there not a way to assure security without so many steps? Is there a way to leave it open longer wihtout having to login again? Thank-you, Paul W. Lane, M.D.

Bob Bunnell, MS, PA-C
bunnellbob@hotmail.com

Thank you for your work. PAs need to know this. We sent this via email to Utah PAs who belong to our professional organization, the Utah Academy of Physician Assistants, approx. 300 members. May I suggest a CME activity for PAs? We invite you to send a presenter to our annual meeting in April.

Easton Jackson
eastonjackson@yahoo.com

86 pages?! Are you kidding. Between the Non-Opioid Pain management tool, Pain management workup and risk assessment and the Brief Pain Inventory (short form (good one, there)), the average physician is looking at 15 pages. Do you honestly think this is going to happen in a 15-20 minute visit? Not a chance. Most doctors treating chronic pain are not boarded pain specialists. With decreasing payments, we don't have time to spend doing all of these recommendations. Unlike the specialists who make their money doing facet blocks, we are left with pain meds, adjuvant meds and physical therapy, all to be crammed into a visit slot, and get paid $50 from Medicaid for a 99214. Sleep studies are a great idea, but they're a pain to pre-authorize with commercial insurance, and impossible on Medicaid. Also, as of December 1st, Medicaid doesn't cover physical therapy any more. My partners and I discussed these guidelines. They are hanging the Internists and FPs out to dry. If I don't follow (and document) every aspect of this program and an adverse event occurs, Keith Barton will have a field day. As a result, my partners and I are plannig to dramatically reduce our number of chronic pain patients who are getting ANY opioids. As such, pain will be untreated, especially for uninsured and Medicaid patients (who can never get into a chronic pain clinic). I appreciate the goals and concerns of the PPMMEP program, but this is a great example of the law of unintended consequences.

Paul Evans
paul_e5@yahoo.com

Back in 1995 my daughter received a prescription pain medication for ovarian cysts while at LDS Hospital. A few days later my wife at that time, and who had been diagnosis with clinical depression told my daughter she had a head ach. My daughter gave her the prescription pain medication tablets which she did not use. When the prescription ran out about two weeks later, my wife started complaining of pain in her pelvis and we went to a gynecologist. She told him the systoms and with out doing a pelvic exam he just gave her the medication. As soon as this doctor stopped writing the prescription she would be off to another. It did not stop until the fall of 1999 while stationed at Biloxi Mississippi Air Force Base did a gynecologist do a complete exam and found that there was nothing wrong with her. I can still remember his words, I am sorry Miss Evans but there is nothing wrong with you and I am taking you off all your medications. Two weeks later as I watched my wife go through withdrawals, she left me and my two children and ran off with a local drug dealer. Luckly I got her returned to Utah, but had no support from her family since her now prescribed adiction form Mississippi went unharolded because the previous prescriptions came from Utah Doctors. After a divorce and lossing my lifes savings to these types of drugs my children from this marriage still suffer from the affects of these drugs, since she still gets doctors to write them. I support any legislative measure that would help stop future drug seekers. They are out there just waiting.

Danielle Adams
danielle.adams@hsc.utah.edu

Regarding management of acute pain, "4) Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where adequate monitoring and assessment for adverse effects can be conducted." What is meant by adequate monitoring? This seems very vague. I am a surgeon, nearly at the completion of my residency, and will likely be continuing to practice in Utah afterwards. I frequently prescribe opioids for acute, post-operative pain. Usually this involves short-acting opioids only, but occasionally a couple weeks of long-acting opioids is warrented, and so I wonder what is meant by adequate monitoring. I think this line needs to be more explicit, or else removed from the reccommendations, as its vagueness could be cause for controversy (and thus lawsuits).

Linda Thomas
rafterl@ubtanet.com

As a retired emergency RN, I understand why this legislation began. However, as the spouse of a patient who is being seen by a responsible, careful physician, and who is on pain meds for chronic pain, I am totally against this legislation. Give us credit for being aware adults who take responsibility for our own health care. Give us credit for finding good physicians who know what they are doing. DO NOT cause more pain to the patient by requiring demeaning, morally invasive testing and questioning. Living with chronic pain is a very difficult way of life. If you have not personally experienced such a situation, I can honestly say you have no idea of the effort involved for the patient just to get up every day and continue living. Having to jump through more governmental hoops is not the cure for the problem of overdosing and illegal use of narcotics. I suggest you concentrate on regulating the minority of physicians who overprescribe and who abuse the system. They can't be too hard to find now, can they? Leave the law abiding, voting citizens alone, both patient and doctor.

Andrew Howells
drewreese@comcast.net

The problem we face is 2 fold. 1st - A few months back after having major surgery, I was in severe amounts of pain. The doctors from the IHC hospitals would only dispense a little bit at a time of the pain medication because of their policies to curb OD and addiction issues. The problem was then on the weekends when the medication runs out and the doctors are not in the their office they tell you to go to the ER which causes very high bills that me as a student and a soldier cannot pay for. Already these medications are so tightly controlled they make it difficult to get a hold of if they are needed, and refills that are needed outside of the normal business hours during the week. This left me on several occasions in pain that was so unbearable that I could not function. the second part the proposed change, is requiring the use of "random drug testing" This is a violation of patient privacy. I understand the need to know if the patient is using other drugs, but then who is the verifying authority. will doctors be required to report the findings of the drug screenings. This will discourage people from seeking medical attention, because doctors will become members of the police force instead of medical providers. In addition, It is an offense to people like myself and my family who are not drug users to be considered Guilty until proven innocent by an invasive collection of evidence just to receive medical treatment. If you want to combat the excessive increase of medical overdose and potential suicide episodes by prescription medication, the most valuable solution would be a massive increase of mental health and social work. I would love to meet with someone at the UDH who is on this panel. I have become somewhat of a subject matter expert on the social implications of this problem. As a Veteran who was on these medications for an extended period of time due to an injury as well as PTSD. I have worked with many addiction cases of fellow soldiers, and I believe I can offer a perspective that may not have been addressed. I look forward to hearing a response.

Timothy Simpson
tim.simpson@mac.com

As responsible citizen, and as an individual who lives with a connective disorder that is progressive, resulting in periods of pain that cannot be explained to someone who has never experienced such it themselves, I find the proposed guidelines to be both capricious and a blatant encroachment on personal privacy that is in no way granted to the state or federal government under any constitutional or executive doctrine. I urge the committee to exercise both compassion and restraint when reviewing this issue. Creating a program that will encourage more people that are nominal law abiding citizens to find extra-legal alternatives to a medical system that is failing them, and by extension turning them into criminals utilizing street grade substances, while at the same time removing the needed guidance of a trained medical professional who is versed in the details of a given patient is worse than poor public policy; it is a sign of a bureaucratic entity that has ceased to serve its public, and has begun to take powers as a despot would. I encourage the committee to maintain the current policies, provide the medical community with meaningful guidance on how to help long term pain patients, and consider adopting the national standards already in place. Thank you for your consideration.

Mary Nester
mnester@health-law.net

I have worked in oncology as a nurse and worked to defend licensed professionals against licensing board as an attorney. Both in Oregon. From personal experience through both my careers I can tell you what we don't need is more regulation that restricts adequate pain control for people who need it. Further, your orthopedic expert is simply wrong in saying that opiates do not work for chronic pain. Opiates are a good, inexpensive and effective treatment for some people who experience chronic pain. Making adequate pain control a social issue will not end the occasional overdose. It will drive good physicians away from providing adequate treatment out of fear. The solution is more physician training in pain management. I suggest you start with your ortho "expert" who is driving this regulation.

Douglas Dewitz
mddewitz@kanab.net

We have a daughter, age 33 who got on perscription drugs starting at age 12. She now finds herself in a spiral of methadone treatment,recurring diseases(Bechets Syndrom),viral meningitis,etc. She cannot afford insurance and has been denied insurance due to pre existing conditions. A recent appointment with a neurologists resulted in him saying her PA could handle everything and he was going to Africa. This was after waiting two months for an appointment. This is a young woman who cannot get the aid you are taking for granted in the guidelines. She has been refused Medicaid twice. There is no recourse. This was the result of doctors perscribing pain drugs and methodone with out understanding the underlying cause of pain management. Now she is up a creek without a paddle. What can we do?

Tony McGuire
tony@paradoxcommunity.com

Reasonable safeguards, I agree with. Regular testing, I agree with. But PLEASE don't limit those of us who need whatever level of pain reliever to deal with severe chronic pain. Please allow the pain to be treated, and catch abusers on the backside. Those who need relief through opioids probably can't wait 2 or 3 weeks while their case is looked over. For myself, I know that if I'm not able to take my medications for 2 days, I don't sleep from then until I do get my medication. Likely crying from the pain rather than sleeping in that interim period. I am 52, and have just started with chronic pain this year (2008). My doctors have tried many different drugs. None are working 100%. 2 nerve blocks have been tried and neither worked. And if my medications were stopped today (one is 180mg of morphine, and that on top of 450mg of Lyrica in combination with 120mg of Cymbalta (Cymbalta enhances the Lyrica)). Some days I'm too off-balance to do much, but at least I know who I am and can usually drive. I would gladly submit to testing in the overall effort to stop abuse. But assume each of us isn't going to abuse and get us our medication - THEN find abusers. Thank you.

Keith Colledge
colledgekeith@yahoo.com

If laws are passed that restrict people with chronic severe pain from getting pain meds, you will see a huge increase in black market and illegal drug use. I for one will not sit idlly by while my 75 year old mother suffers due to some crap laws being passed. I will contact a heroin dealer in her behalf.

Janene Davis
jdxmas@hotmail.com

This is outrageous! this infringes on civil rights! I believe this is between the Dr. and patient and culpability should be removed from the doctor to the patient when long term opiate use is considered. What's happening to our constitutional rights?

George Kelly
lewlclick@gmail.com

I am concerned about the rights of patients. If at any time a patient is asked to submit to any type of drug screen, urine analysis, etc. in order to receive a prescription then government is overreaching. These types of tests are for accused criminals, parolees, and inmates of our correctional facilities. Only under the most extreme circumstances where the interest of justice is concerned should the government seek to compel its citizens to submit to such a demeaning examination of their person.

David Feeger
feeger@peoplepc.com

I see no reason for the state to get more involved with the pain med issue. The Utah pain clinics are doing an excellent job of screening patients and most require phycological screenings/ physical therepy long before the prescribe opioids. They also try other drugs long before prescibing them. Let the doctors do their jobs and stay out of it unless they go crazy prescibing 1000's per day. You already have that law in place and changing it again will only hurt those who honestly need help.

Windy
breezzymom@msn.com

My very personal opinion regarding this matter is that more opportunity for help with getting off of these medications is needed. This topic hits very close to home on so many levels. I have had 3 c-sections and refuse to take any of the medications when I leave the hospital because I am so afraid of becoming addicted, like some very close to me are. In a lot of cases it starts so innocently: a car accident, a sports injury or getting hurt at work and then before they know it they are addicted to these pain pills. I feel like they would really like to be off of these medications that control their lives, but there are not programs readily availible to do this. Prescription medications control your life just like any other drug and many of them are financially ruining families. I would love to see more money spent on helping these good upstanding people, that is what most of them are. These people have jobs, families and lives that are being controlled by prescription medication and are given little resources to get out of the tangled web. thanks!

Curtis
pokergooch1966@hotmail.com

I dont mind signing a contract or giving urine samples. But what I do mind is having to see a specialist to prescribe over a certain amount. I dont have insurance. I also have tried to see a pain specialist, it took 6 months and hundreds of dollars. My doc worked in a pain specialists group for a while. that group disbanned and he absorbed some pain patients. i am one of those. Please dont put restrictions on me! Ive followed the docs rules for years, taken as prescribed. never a problem. Maybe these rules could be for new patients, but not established.

Dianne Sue Player
rodandrelic@msn.com

I believe the doctors should be closely looked at to make sure they are not running a "mill." But I do not believe government can "randomly" test its citizens for any reason! Stop chipping away at our rights to privacy.

Brian Gasser FNP
briandellg@hotmail.com

Make all opioids including hydrocodone CII. Make tramadol a schedule drug. Take away the ability to get refills on ALL schedule drugs.

Lee Stokes
stokesld@ldschurch.org

Before the guidelines are published and recommendations for legislative action are made, please consider expanding the guideline recommendation panel. It should include someone perhaps better versed in the diagnosis and treatment of Peripheral Neuropathy. I don't recognize any of the names listed. See the following URLs for possible participants: http://www.neuropathy.org/site/PageServer?pagename=phy_us_utah and http://www.neuropathy.org/site/PageServer?pagename=Resources_PNCenters. You may also wish to involve patients who actually suffer from chronic, non-cancer pain. There's no substitute for direct information. Now for some personal and anecdotal notes. By means of a skin punch biopsy, I was diagnosed with Idiopathic Small Fiber Neuropathy eight years ago. My own experience, and the experience of others I've talked to who have Neuropathic pain from a variety of causes (diabetic PN, Radiculpathy, Cancer Chemo and Radiation treatment, etc) is that Acetminophen is unlikely to be helpful. Yet page 37 of the proposed guidelines recommends it as front-line treatment. That recommendation could only have come from someone who has never treated neuropathic pain--or if they tried, the patient went elsewhere because the doctor was an idiot. Now, in fairness, most people I've talked with receive good results from one of the off-label uses of the anit-convulsants alone or in conjunction with tri-cyclic anti-depressents. For others, tramadol is quite effective. However, there will always be those such as myself who responded very poorly to these medications and are left with opioids as our only alternative. My concern is the proposed guidelines will make it difficult, if not impossible for us to obtain these medications when we clearly benefit from their use. Were it not for hydrocodone, I would have a very difficult time holding down a job--my my feet are too painful to stand or walk on otherwise. And at age 53, I'm far too young to consider retirement or disability. I think perhaps more stress should be placed on pain management specialists working WITH the family doctor rather than suggesting these specialists assume all the care. As the guidelines indicated, there are places in Utah where access to pain management is limited because of distance or availablity. Another thing, the guidelines seem to be very Medicaid-centric. Those of us with private health insurance have to be treated according to our plan guidelines. All the State resources listed are actually rather limited and not very good.

Jan Jenkins
janjenkins11@comcast.net

I think physicians should always check the patient's name with the narcotic data base to make sure they are not obtaining "extra narcotic meds" However, people can send in friends or family members to get prescriptions for them if they want. I think random blood or urine tests carry it too far. Why should people on pain meds be treated like criminals when most of them arent? How are you going to prohibit the use of alcohol and pain meds? Go home with the patient? Thanks

Heather Todd
heather-todd@hotmail.com

I would like to comment on the proposed board of Doctor's who are going to recomend doses of opiod's that they deem apropriate to treat individuals.

Francie Marden
buzzdvm@comcast.net

I am a Registered Nurse. I deal with this issue everyday. I am a Care Manager for Selecthealth and would very much like to share some ideas.

Russell Hunt
russellhunt@yahoo.com
carbonmedical@gmail.com

I work in a small clinic, 1 provider, 1 nurse and 1 receptionist. Have you considered all of the work and documentation these guidelines will impose on small clinics or solo practices? I currently follow most of the guidelines, but can't find enough time to adequately document everything.

I work with many uninsured and impoverished patients. A homeless shelter is across the street from our clinic. Treatment of these patients can sometimes be very difficult. If they have severe chronic pain they often go untreated except for self-medication with alcohol or something a friend will give them. Getting an accurate and up to date history is impossible. Doing a "comprehensive" evaluation is limited by money and time. Many of my patients don't own a car and can't afford any special studies or referrals. They can't even afford to go 10 miles to the nearest pharmacy. The guidelines look good on a superficial level, but in the real world people don't always have money and resources.

Richard M. La Jeunesse
r.lajeunesse@comcast.net

If stricter guidelines are instituted for the use of opiates in treating chronic pain, then as part of the guidlines there must be available accessible and equally effective alternative treatment. Without accessible and effective alternative treatment chornic pain patients will be at risk for resot to: (1) alcohol abuse; (2) street drug abuse; (3) over the counter medication abuse, and; (4) suicide. None of these alternatives can be any worse or more devastating than opiate addiction with its current mortality rate. At least with a medical doctor prescribing opiate pain medications there is a gate keeper with some expertise. Also, unless the guidlines specifiy that removal from opiate treatment must be accompanied by an accessible and effective alternative, insurance carriers will cut the patient off from payment for other forms of palliative treatment.

Trent Hanson
uhd@hansonclan.net

Thanks to the SLC Tribune I discovered this document and have the ability to make comments. If not for that article this document would pass unnoticed by the public. The guidelines being proposed contain many good things, and although I could certainly go through line by line I doubt it would have any impact so I will focus on the broader implications of what is being produced. All major Health Agencies, most medical societies and every single clinical study has shown that pain is under-treated in this nation. Some organizations even label the level of under treatment as "epidemic" and catastrophic. These clinical studies and others have also shown across the board hat acute pain, cancer or otherwise, and chronic pain damage or destroy the life quality of the individuals experiencing the pain. The pain also causes more complications, more infections and reduces recovery rates. Studies have also tied pain to many other clinical problems. None of this should be unknown to the panel, but outside a few small paragraphs these critical facts are barely acknowledged, identified and emphasized in the policy. My personal experience with pain has shown me that the medical field is almost uniformly unsympathetic (with rare exceptions), more scared of other government agencies than of treating pain and I have no doubt that the attitudes toward pain and treatment with opioids is causing deaths. My anecdotal story is of someone who developed a massive headache on a scale I doubt any of you could even imagine. After two months my pain was tied to pseudo tumor cerebri and elevated spinal fluid pressure. This acute pain was focused in the sinuses and temples and all clinical tests including CT, MRI and blood showed no evidence of a condition. Only after two months and the ultimate destabilization of my vision did a diagnosis surface. At the time I was probably less than a day or two from suicide. My behavior during this time fit with every single pattern of a drug seeker and certainly met those your document lists as serious warning triggers. Had any of the doctors that were kind enough to give me opioids in the run up to the diagnosis followed your checklist, before prescribing, I would have been denied and would be dead by my own hand. Years later I'm now experiencing a similar situation where I have chronic pain with no apparent explanation for the reason. Again using the checklist in the document would label me as a warning case. I'm sure there are Doctors on your committee that wouldn't even consider prescribing. Without safe and effective treatment with what god gave us to control pain I don't know how I would or even if I could handle the simple chore of existence. Although my revised life situation would impact my will to end my life there have been half a dozen times when the pain and the limitations it imposes on my life have gotten bad enough that I have placed serious thought to the ultimate solution. Three years in I'm still looking for that silver bullet of a symptom that will reveal what is actually wrong with me. I've read so many medical publications I feel like I could get a degree. Outside my singularly uninteresting experience which will have little weight on this document or it's committee I have a simple request and comment. Even with the vast years of combined experience on this committee I hope to remind you not of what you know but what you don't know. I ask you to remember what you learned in medical school about how much you didn't learn and in consideration of how complex of a system the body is how little each of you truely knows about the human

body and the diseases that afflict it. I ask that you take this understanding into your heart as you revise a document that suggests stringent guidelines and strict control of drugs that our own studies have shown are under prescribed and under used. And recognize that in the fear of addiction you are willing to damage the lives of every single person afflicted by a condition or disease that medicine doesn't recognize or understand and will you will directly harm people. I would also ask that before publishing arbitrary use rates mandating pain specialists you actually do the math on the number of patients in chronic pain, divided against the number of pain clinics and pain specialists then multiplied by the number of visits per year you are requiring and see how many hours each day you are going to be requiring for each pain specialist to work to meet the guidelines of your recomendations. That there isn't more uproar from the specialists alone is shocking. It's not surprising that these conditions are clearly being used as the backdoor method by certain uncaring and unsympathetic doctors on the committee who are trying to block the use of opioids in treatment through this document. Finally, remember that the document you produce isn't just guidelines. Like many published industry guidelines it will become the standard of care, the expectation of the insurance industry and the measure by which your profession will be held in the courts of law. Please weigh your product against the lives it will impact. Thank you.

Nolan Money, M.D.
(nolanmoney@comcast.net)

I have read the recommendations and I think they are very appropriate. Managing chronic pain patients is the most challenging aspect of my practice. These guidelines well be very helpful. Thank you for your efforts in putting this together.

Heather
cavaliergirl714@yahoo.com

I have been taking oxycontin for over ten years, after a period of time and as my pain grows worse my Doctor has increased my medication. I have always taken my medication as prescribed, I understand that alot of people dont, they make the rest of us look bad. I have a suggestion, Maybe the patient should schedule their appointment with the Doctor when it's time to take thier Medication, be required to take said medication in front of Doctor and then be monitored by Doctor for about an hour or so, if the patient is being deceptive about the amount of meds. he or she is taking, the Doctor would be able to notice a change in behavior and take appropriate action. I decided to take my meds. in front of my Pharmacist because I got tired of him giving me looks like I couldn't be taking all of these meds.,so I explained to him what I was doing, took my pills and had to wait in the pharmacy to take care of insurance purposes. He kept coming over and asking if I was o.k. ? After that day he no longer gave me a scrutinous look, in fact he was more understanding and helpful than before. Another point is if insurance companies start deciding how much medication patient's should be taking you may have alot more deaths from suicide, If I didnt have my medication to control my pain I would have no life, my quality of life would not be worth going on.Every person is different in the amount of Medication they need to control their pain, it's not a one size fits all. I am afraid that Insurance companies will eventually control how much medication can be prescribed to an individual and this would be a tragedy, Thank You For Your Time

Jean Palmer
jeanpalmer72@hotmail.com

I am in recovery after being addicted to pain mediation. It started with migranes that I'd had for years but before I was through the migranes weren't the problem, it was the medicaton. I had only 3 doctors; all 3 knew what they others were prescribing so I felt safe and that the "doctor knows best." It is true, no one made me take the pills and I was completely addicted because of my own actions. However, after I was in treatment I found out how dangerous the combination of these drugs were and my counselors said they didn't know how I lived through it. One doctor had me on 5 different medications that are sedating. Another had me on 3 Class I pain killers at one time. And then, from the other one, I would get demoral at the hospital about any time I asked for it. Please do something to stop this. Some friends that I was in recovery with have died from overdoses after. The sad thing is that they worked really hard to get out from under it and then went back because the addiction is so strong. Do everything you can!

David R Hales
dhales@comcast.net

I appluad the Department of Health in their effort to control the misuse or illegal use of narcotics. I have seen first hand the damaging effects drug abuse can have on familiy, communitiy and society in general. I have reviewed the distinguished list of individuals compiling the proposed regulation. One observation I have is that the list, while distinguished, is missing one critical viewpoint, that of a recovering drug addict. The recovering addict can give an entirely different viewpoint to this problem and to prudent solutions, in addition those listed. The regulations, while a good start, fail to address those in society, namely addicts, who would do just about anything to get drugs. The idea that all in society are honorable law-abiding citizens and have the desire to do what is right is good in theory, not practicalble in application. When signing a contract to not abuse drugs or alcohol as a requrement to get drugs seems somewhat nonsensical. When needing relief from pain or the next fix, the signing of a contract to get more drugs seems comical at best. How does a drug test distinguish between a prescription drug and the same drug bought illegally on the street.? I would suggest that a large portion of drugs being abused are illegally obtained on the street. The idea in our local microcosm is that the use of prescription drugs are okay because a doctor prescribed them. That idea is further misconstrued that if a prescription drug is okay, then if the same drug is obtained on the street, that is also acceptable. The idea that a family member or neighbor is a drug addict needs not to be spoken in whispers and disgust, but out in the open with the support of the community in a sincere gesture of caring. The idea that this issue could not be in our community, because we adhere to good principles needs to die an ignominious death, much the same as many of our friends and neighbors have from drug abuse! The current DOPL program listing pain medication users will work, if used. Education in the medical field will help reduce the problem. Why does a Doctor prescribe 30 Lortab to a patient that has an ingrown toe-nail removed, as ours did? I am not certain that the medical profession clearly understands that these opoids are extremely addicting and next to impossible to quit using once started. Please know that I am passionate about this issue, for the last 9 years, my family has hopefully seen all there is to see when it comes to drug addiction.

Morgan Wolf
morganblaidddu@yahoo.com

Sirs; By your own admission, 50% of the prescription drug-related overdoses are NOT people who are prescribed opioids for chronic pain. Does it not make more sense to address the 50% who have no reason to have the drugs first, rather than attacking those of us, like myself, who are in chronic pain and take massive doses of opioids *as prescribed* for pain management? The levels of opioids and other medications that I, and many like me, take on a daily basis, your proposed "random testing" won't determine an increase-we are already at the edge of dangerous dosing. We have to fight for State Assistance, we have to fight for YEARS for Social Security Disability, and we have to do it all while we are in agonizing pain, a drug-induced haze, or both, and NOW you want to add one more hoop for us to jump through? Don't you understand that we can't jump at all, let alone through these new hoops you wish to add? Leave us chronic pain sufferers alone, and go after the teenagers holding "pharm parties" and overdosing on medications that they stole from one of us! For the record, I have severe spinal arthritis, and I take the maximum dosage of methadone allowed by PCN every day. I am not addicted to the methadone, because I don't need the pills- I need the pain relief. At least once a month, I skip my medications, to test myself for addiction. Every time I do so, the result is the same- no withdrawal symptoms, no burning need for the drugs, nothing beyond the pain that requires me to take the drugs in the first place. As it is, recent minor surgery involving having my right thigh cut open was substantially less painful than the back pain I deal with on a daily basis, I don't need your help to manage my chronic pain medication, that is what I have a certified specialist for. To be perfectly clear- I believe the proposed restrictions on prescribing opioids to be an ill-concieved, poorly planned, and outright cruel and unusual punishment of those of us with legitimate need for these medications. It seems obvious that since you haven't been able to do anything about illegal narcotics and illegal use of prescribed opioids, you are attacking the one group that you know can't fight back- those using prescription opioids *as prescribed*. We are doing all that we can to survive day-to-day as it is, we don't need you to make it more difficult, with "random testing" that will only show what you already know-we take a LOT of opioids. Stop this attack on chronic pain sufferers, we have enough to deal with. Go figure out how to stop the people that are stealing prescription opioids for "fun".

Sharon Forbes
sforbees@msn.com

My son has suffered from migraines since he was 10 years old. They had subsided for a short period of time but then he was rear ended by a drunk driver and they started up again and he has suffered ever since, he is now 26 years old. He also has had kidney stones 3 to 5 times a year since he was 20. These are painful and serious conditions that require pain medication that is effective when administered the first time. Some pain medications work well and quickly, others don't touch him. He is a big man, 6" 4". I have taken him to the ER when either a nurse or doctor look at him and determine that he is looking for pain medication and totally treat him with no respect or compassion. I have been in tears, pleading with them to help him. This has had a very negative effect on all of us. He has apparently been put on a list that the DEA keeps because of his visits to the ER. He has FMLA through his work for his medical problems. He has been a good loyal employee of the same large company for the past 4 years. He and his wife have purchased a condo and are trying to live a normal life. I can't tell you the number of times he has to cancel family activities because he either needs to make up hours at work, has a migraine, kidney stones or is at the ER. Even with insurance this costs them money and has a huge impact on their lives. To be treated as a drug abuser just adds insult to injury. Please do NOT affect his life style even more by making him be drug tested, taking more of his precious time away from his job and family. Something needs to be done, but to the real abusers, not the patients who are in need of medication for pain. NO human should be treated so inhumanely. Thank you for your consideration and compassion. Sharon Forbes

Doug Lawrence
douglas@lawrencefamilyphotography.com

I would like to participate in this committee. I am go to Pain Management and take Opiods for severe back pain. I am afraid that these requirements will destroy the quality of my life and those in my situation. It took 10 over ten years of doctor visits insisting I had problems before they would even do an MRI. They thought I was just a drug seeker. When the MRI was done, they found a birth defect was causing the pain, plus degenerative conditions caused by the defect. Citizens should not be treated like junkies because they need medication. You wouldn't accuse a diabetic of needing a fix of insulin. I have a permanent medical condition that needs medicine the same as they do. I have a handicap plate for my car, yet I still have to get random drug screens by my clinic to prove I am not abusing my medicine. It is bad enough that insurance companies decide the course of treatment for most conditions based on what they will pay. Now the state is going to get involved and regulate how they treat my disability. It is time to allow doctors to treat medical problems rather than the government.

LAWRALIE ERSKINE
lawralie@hotmail.com

I have had several major surgeries. The doctors are usually reluctant to prescribe medications that will ease my pain. I don't want to be required to take drug testing especially when I don't feel well. More attention should be placed on the DEA# and which prescriptions are being filled by each patient. Doctors should ultimatly be responsible for the control of prescriptions. Doctor shopping can be avoided by tracking the medication being filled by each patient.

EDWARD MAHON
emahon@centurytel.net

I was a caregiver for many years and my wife used Demerol to relieve her pain. Even from the beginning, it only took the edge off. This, of course, was the best she could do. The only reason the doctor prescribed this medication was because my previous doctor, Dr. MacKay, had retired and had prescribed it. Otherwise the new doctor.Dr. Southworth. would not have. You don't know until you've been there and seen the ongoing suffering.

David J. Peifer
david.peifer@va.gov

Of note, many of the drug deaths the Department of Health attributes to overdose with opioids were actually mixed drug deaths, the most common second substance ingested in addition to an opioid was alcohol. Given the published rate of complications, it is likely that non-steroidal anti-inflamitory drug (NSAID) induced gastrointestinal bleeding caused more deaths in Utah than the opioid analgesics in the time period reported by the Utah Department of Health. Medical and pharmacological literature has noted that there is no upper limit of the dose of opioids in the treatment of chronic pain. The correct method in use of the opioids is to increase the dose until no addititional pain relief is provided by an increase of the opioid dose, or unacceptable adverse drug effects develop which limit the dose. Setting an arbitrary upper limit on the total daily dose of opioid will leave patients with inadequate pain control. The goal of treating moderate to severe pain with drugs other than the opioid analgesics appears laudable, however, when the level of pain is more than moderate in intensity, no class of drug other than the opioid analgesics are effective. Virturally all primary care and pain medicine specialists use adjunct medications (anticonvulsants, antidepressants, benzodiazepaines, etc) in the treatment of chronic pain, however, these drug classes are adjuvants to the opioids, not substitutes for the opioid analgesics in the treatment of chronic pain. In summary, the proposed policy contains treatment recommendations are not evidence derived, and adopting these recommendations would reduce the effective treatment of pain.

Michael Hoffman
michael.d.hoffman@hsc.utah.edu

As a patient that has had dozens of kidney stones, back problems, multiple surgeries, a rare form of arthritis and 2 bouts of pancreatitis (stone left behind during gallbladder removal and drug induce from byetta) I can tell you how much these pain-relieving drugs are needed. I have good medical insurance, but it July I will likely loose my job. Currently I see my GP and Rheumatologist every three months and have for 6 years, however without out insurance I will have to cut back. Also since I have several predisposing diseases will not likely be covered for these conditions. I have a problem with the drug testing and think it will fail for some of the following reasons. Who is going to pay for testing a patient without insurance the medicine is only $30 for generic? If I'm at home and have taken medication I will not drive to your location are you going to send someone to my house with the states budget short fall? If you tell a patient to come get test and they were abusing drug could they not just clean up for the test. How would you test for alcohol if they have not had a drink within 24 hours a more expensive test? Or use a test that does not prove that drink, but only that they may or have another condition. I feel as a patient who has taken pain medication for almost 30 years that think that several frank discussions about how the pain medication works and how the patient should use it would be more beneficial. Including telling the patient to hide their medication to avoid conflicts when guest visit. It was only when I started seeing the University of Utah's Rheumatology that the doctors even ask about my pain level, how the pain was being controlled, and would ask if I have any questions about how the medication works. Having worked in research for the last 18 years I had to do the research about these drugs on my own and most patients do not know how to go about searching for help. I applaud what you are trying to do, but feel better patient education and communication with the doctor would be more effective, cost effective and will help prevent some of the accidents that have been in the news. Thank you, Michael Hoffman

Sarah Goodlin
sjg-pcer@comcast.net

The guideline background states that no evidence exists to support opioid therapy for chronic pain and cites a reference "Von Korff & Deyo, 2004" that is not a peer-reviewed published paper. The guideline background should state this and clarify the origin of this statement. Many patients do well with chronic opioid therapy for chronic pain. Many elderly persons have clear contraindications to other possible medications such as NSAIDs (hypertension & heart failure for example are epidemic in the elderly). Opioid therapy has been recommended by the American Geriatrics Society (in published statements) as appropriate for management of pain in the elderly, expecially for conditions such as osteoarthritis.

William Forbes
wmdforbes@gmail.com

My 26 year old son has suffered from migraine headaches and kidney stones for about 10 years. He has needed emergency room care on many, many occasions such as when the 'attack's' are late at night and doctors are closed. Though he is now married, prior to that I accompanied him to the ER and witnessed some of the most condescending, patronzing, accusatory behavior imaginable. I have had arguments with medical personnel over the mistreatment or lack of treament for my son on more occasions than I care ot count. Our culture has condemned him because he is young and if he needs narcotic pain killers, he must be a doctor shopping drug addict. Our legal system has created a list of people like my son, that is presented online to every doctor who treats him, and presumes his guilt before he is even spoken to. And it is clear that doctors who treat him regardless, risk their credentials and even prosecution if some self righteous do-gooder decides to make it difficult for that doctor. As you can imagine, this type of treatment is degrading and demoralizing, and likely contributes to the severity of his pain if not the frequency. Now some other self righteous do gooders want to make it even more difficult and degrading for people like my son to get treatment. Certainly we need to take precautions and have compassion for those who become addicted, but this new set of guidelines do so at the expense of the individual who has chronic pain, and make lead to abuses by those who have been refused treatment, or who can no longer brook the abuse meted out by our system. Please reconsider at least the suggestion that these people should be randomly tested. To treat them like criminals makes their lives just that much more difficult because life is just to darn difficult to live .

Brad Thomas
icaknow@yahoo.com

Rarely do arguments concerning overdose deaths address the core problem with overdose deaths and that is the people who seem to succeed at killing them selves are not the people the medications are prescribed too. I have chronic arthritis (spinal) which makes life under most instances less than pleasant. Making it more difficult to obtain the needed prescriptions or amounts puts extra burden on those of us who get and use the medications properly. An other thing that is counterproductive is to threaten all physicians because of a few Dr.'s bad judgment. If they were all five years old, that may be a good place to start but they are not and the last thing I want is for my physician to be worried about prescribing medication to me! I don't know what the answers are to many of the questions but making it more difficult for the physician to prescribe or making me have to see my Dr. more times a year are not good alternatives either. My arthritis is not going to go away nor is it going to start hurting me less. Thank You, Brad Thomas

Fred Davis
floaterslc@yahoo.com

I have 20 years of experience in managed healthcare as a systems analyst/programmer, consultant, data review and analysis, claims review logic, fraud and error detection, system and forms design to minimize errors and patient satisfaction methodology. I would be willing to be involved with whichever committee or workgroup that needs my abilities, experience or knowledge.

PHONE CALL

Erin,

A man called me this morning wanting to comment on the public guidelines based only on information he received from the article that was written in the Salt Lake Tribune 1 or 2 weeks ago. He decided it would be easier for him to verbally give his comments than submit a written comment. Here are his comments based on the notes I took from our phone conversation:

He is a chronic pain sufferer, has never received full pain relief, but because of pain medication has been able to function.
Utah needs to look at the society here, the state we live in, suicide rates are high because of the tremendous pressure from the church. If people can't live up to it they look for a way out.
These guidelines are a knee-jerk reaction to the problem.
He has a prescription for fentanyl, but also drinks a glass of red wine with dinner because of the benefits of reducing risk of heart disease. He couldn't sign a contract saying he wouldn't drink alcohol while taking pain meds.
Drug testing just stigmatizes the pain patient, and only adds to the fear that primary care providers have in prescribing pain meds.
There aren't enough pain specialists here in the state to accommodate all of the pain patients.
When you developed your advisory committee for the guidelines did you include someone who is a pain patient?

Those were the main comments he had. Basically very upset about how the article was written. He hadn't done any follow-up research into the guidelines, such as reading them.

I let him know that the guidelines are just recommendations, not mandated policy. I thanked him for his comments and let him know that we would consider them before the final draft is published.

Jonathan

p.s. We've received a lot of feedback just from that one Tribune article because of how sensational it was.

Heather Christensen, PA-C
hdhooverc@yahoo.com

Wonderfull! These are the guidelines that I already use in my practice and have been trying to teach my supervising physicians and other providers in my former practice to use also to help protect themselves and their patients.

Christopher Kottenstetter
Christopher.kottenstette@alpharma.com

Page 8/59
Summary Recommendations
Opioid Treatment for Acute Pain

Addition of the legal ramifications and letter of the law punishment for sharing medications should be addressed and the patient advised of these laws as many patients and providers are unaware of what the actually say or how much trouble they could be in legally. Assistance from law enforcement representatives on the guideline panel may be able to help with this.

Page 8/59
Summary Recommendations
Opioid Treatment for Chronic Pain

5) The patient should be informed of the risks and benefits and any conditions for continuation of opioid treatment, ideally in a written and signed treatment ~~contract~~ Agreement and plan.

10) An opioid treatment trial should be discontinued if the goals are not met and opioid treatment should be discontinued at any point if adverse effects outweigh benefits or if dangerous or evidence of illegal behaviors are demonstrated.
11) Clinicians should consider consultation for complex pain conditions, patients with serious co-morbidities including mental illness, patients who have a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her abilities to manage the treatment.

Comment [ck1]: Complex should be defined to avoid ambiguity. Complexity should be based on the providers expertise and experience in the area, and if lacking the needed expertise one should refer. This complexity could vary as in a newly graduated provider, vs. an experienced one, or complexity could be used as a way to "dump" patients on other providers because the provider does not want to treat them for a variety of reasons. The latter should be guarded against in defining this term with panel input.

Page 10/59
Panel composition
The Utah Department of Health convened two multidisciplinary panels (see Appendix 1 for complete list of panel members). The Guideline Recommendation Panel convened on four (4) occasions between May and July 2008. Their purpose was to review the evidence and formulate recommendations based on the evidence in the selected guidelines. Each member signed a Conflict of Interest disclosure. No conflicts were reported.

Comment [ck2]: Appendix 1 not found as part of this document.

Page 13 (top of page)
Before prescribing opioid treatment for chronic pain:

Long-term use of opioid medications to treat chronic pain ~~safetly~~ safely requires commitment of adequate resources for regular monitoring and evaluation of outcomes and occurrence of adverse consequences.

Page 13/59
Panel composition
Added to bullet points (after Assess for presence of medical condition…..

- Assess for family, cultural, and social conditions that may complicate opioid

management.

- Assess the severity of pain, functional status of the patient, and the ~~patients~~ patients' quality of life using a method/instrument that can be used to evaluate treatment effectiveness.

Page 14/59
Consider alternative treatment options:
After 2.1 Recommendation

Opioid medication may not be the appropriate first line of treatment for a significant proportion of patients with chronic pain. Other measures, such as NSAIDs, tricyclic antidepressants, ~~antiepilepitics~~ antiepileptics, and non-pharmacologic therapies (e.g., physical therapy), should be tried and the outcomes of those therapies documented first. Opioid therapy should generally not be considered as initial therapy and should be used only after alternative approaches have been given an adequate trial and have failed. Opioid therapy should be considered as the initial therapy only in very selected circumstances, such as for a patient who has demonstrated sustained improvement in function and pain level in a previous opioid trial and who has no risks or contraindications to opioid therapy.]

Comment [ck3]: What is considered an adequate trial? This leaves a lot of room for interpretation.

Page 15/59
Paragraph above Recommendation 3.3

Immunoassays can be done in the office. These determine if opioids are present and can, depending on the test used, identify specific opioids present, but have high fale positive and negative rates and must be interpreted by an informed provider knowledgeable in their use. ~~but do not identify specific one, which can s~~ Subsequently, confirmations should be done by laboratories using more sensitive methouds of detection such as HPLC, GC/MS or other advanced technologies ~~be determined by confirmatory laboratory testing~~. However, in many cases, going over the results of the initial in-office test carefully with the patient can eliminate the need for confirmation testing. It is extremely important to keep in mind that immunoassays have both false positive and false negative results. Over-the-counter medication, for example, can cause a positive result [5]. The prescriber ~~may want to~~ should consider confirmatory testing or consultation with a certified Medical Review Officer if drug test results are unclear [5].

Page 15/59
Paragraph just after Recommendation 3.3

Most patients requesting treatment for pain are legitimately seeking relief of the pain. However, a subset of patients who present seeking treatment for pain are seeking drugs, for recreational use, to support an established addiction, or profit. Finding that the patient has received controlled substances from other providers in the past can alert the provider to this problem. The State of Utah's Division of Occupational and Professional Licensing (DOPL) maintains the Controlled Substance Database (CSDB) Program, which is a ~~queriable~~ searchable record of all prescriptions that are filled in the state for controlled substances. The Utah Controlled Substance Database Program was legislatively created and put into effect on July 1, 1995. It is used to track and collect data on the dispensing of Schedule II-V drugs by all retail, institutional, and outpatient hospital pharmacies, and in-state/out-of-state mail order pharmacies. The data are disseminated to authorized individuals and used to identify potential cases of drug over-utilization, misuse, and potential abuse ~~over prescribing~~ of controlled substances throughout the state. This database is accessible to all controlled substance prescribers online (www.csdb.utah.gov). A "Getting Started" presentation is available to orient first-time visitors to the site. Each prescriber may also designate one trusted assistant privilege for accessing this database on his or her behalf.

Comment [ck4]: When followed by the previous sentence it implies addiction, recreational use, or profit as THE motive for multiple provider Rx's. Often, it is the combined undertreatment of pain and the patients simple desire to get adequate pain relief . I would consider re-wording to indicate that there are multiple reasons for these findings, and that theses issues need to be discussed candidly w/ the patient to determine the cause.

Comment [ck5]: Really? Do out of state mail order pharmacies have to report? Do they? Do they even know they have to? I would think they may be required to report in their dispensing state if a PMP is in place, but not for out-of-state delivery. My ignorance here. Just want to verify this.

Page 18/59
Paragraph after Recommendation 5.1

The patient should be counseled about the risks of developing tolerance, physical or psychological dependence~~, and~~ withdrawal symptoms, ~~as well as~~ how to use the medication, and possible adverse effects [4, 5]. Adverse effects can include endocrine, immunologic, hypogonadism, ~~with secondary~~ osteoporosis [3], opioid-induced hyperalgesia [3, 5], allodynia [5], abnormal pain sensitivity [5], ~~and~~ depression [8], sleep disorders, constipation, and others.

Patients should be informed not to expect complete relief from pain. The excitement and euphoria of initial pain relief that may occur with a potent opioid can lead the patient to expect long term complete pain relief. Without careful guidance this may lead the patient to desire excessive dosing of opioids and to disappointment.

Cognitive impairment may occur when patients are taking opioid medication. Therefore, discuss with patients the need to avoid operating motor vehicles or equipment or performing other tasks where impairment

Comment [ck6]: Maybe just leave it as adverse effects and highlight the long list elsewhere (i.e. in the informed consent form) which may be included in (or probably better separated into a separate document from) the opioid agreement.

Comment [NJW7]: 1.Daniell HW. Opioid Endocrinopathy in Women Consuming Prescribed Sustained-Action Opioids for Control of Nonmalignant Pain, 12 October 2007, *J. Pain* 9(1):28-36.

would put them or others at risk until the patients dose is stabilized and the effects of the medication are known and stable.

Comment [ck8]: From a legal perspective (since this document is generated and will be used by multiple stake holders including law enforcement personnel) it may be worth addressing the literature on opioid use and cognitive and physical abilities (driving). Otherwise, w/o qualification, this statement will lead to potential undue litigation/prosecution.

Page 19/59
2nd paragraph after Recommendation 5.3

The prescribing clinician may consider requiring that the treatment plan, be documented in the form of a treatment ~~"contract" or~~ "agreement" that is signed by the patient.

Page 29/59
GLOSSARY Section

GLOSSARY	
Term	**Definition**
Aberrant drug-related behavior	A behavior associated with drug abuse, addiction, and diversion.
Abuse	Maladaptive pattern of drug use that results in harm or places the individual at risk of harm.
Addiction	A primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.[132]
ADL's	Activities of Daily Living (dressing, eating, showering, shopping, etc.) ~~Activities of daily living (dressing, eating, showering, shopping, etc.)~~
Breakthrough pain	An acute worsening of pain in a person with chronic pain. Breakthrough pain may occur at anytime and without warning. This is in contrast to Incident Pain which is generally preceeded by an activity or event that initially may not be predictable, but can be predictablely repeated
Comprehensive Initial Evaluation	(We are developing a checklist tool for this…should it also be defined?)
Diversion	The intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution.
Hyperalgesia	Increased or heightened sensation to pain or pain stimulation.
IADL's	
Misuse	Use of a drug in ways other than prescribed by a health professional.
Physical dependence	A state of ~~adapation~~ adaptation manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.[132]
Pseudoaddiction	The development of abuse-like behaviors due to unrelieved pain, ~~and~~ that should ~~by~~ be eliminated by measures that relieve the pain.
Trial Period	(needs complete definition)
Tolerance	A state of ~~adapation~~ adaptation in which exposure to a drug induces changes that result in a diminution of one or more opioid effects over time.[132]

Page 55/59
Paragraph after Absolute contraindications to opioid prescribing: Discussion

1. *Allergy to opioid agents*

Morphine causes the release of histamine, frequently resulting in itching, but this is not an allergic reaction. True allergy to opioid agents (e.g. anaphylaxis) is not common but does occur. Generally, allergy to one opioid agent does not mean the patient is allergic to other opioids; also switching to an agent in another opioid drug class may be effective. For example, if a patient has a hypersensitivity to a phenanthrene, then a ~~diphenylheptane~~ diphenyl heptane drug may be tried. (See table below.) When patients report an "allergy" to all but one agent (such as meperidine), the presence of a substance use disorder should be considered. Consultation with an allergist may be helpful to resolve these issues.

Dr. Lynn Webster
lynnw@lifetreepain.com

Dr. Rolfs,

Attached is a letter from Dr. Perry Fine and myself to you regarding the opioid prescribing guidelines. I have also attached an op-ed which will appear in the journal of Pain Medicine in about 4-6 weeks and the AAPM response to the Washington State opioid prescribing guidelines that was previously published.

I hope you will find these comments useful in your deliberations and leadership of managing a difficult problem for our state.

Please see the attachment for news out of Washington state. As I have said, "recommending" (which is like mandating if included in the UDOH guidelines) a pain specialist consultation for patients on or above 120 mg of morphine equivalence is problematic. I do not believe it will reduce deaths and it is impossible to implement due to the few "pain specialists" available to see patients within the required managed care panels. It is likely to have a "chilling effect" on appropriate pain management. It will give payers a reason to deny coverage to patients who may need it. More patients will suffer from delay in treatment or inadequate treatment. As this article suggests, the idea of using coversion tables to determine equivalence is a flawed concept. There is no scientific basis to support the conversion tables, and this is one of the reasons for some deaths.

There is nothing magic about 120 mg. In some patients, 30 mg of methadone can be lethal. Primary care physicians (all physicians) must be taught how to use the pain medicaions safely at all dose levels. We must keep our focus on what the evidence is (albeit small and incomplete) that is contributing to the deaths and not on how to save insurance companies money.

Attached is a letter from Dr. Perry Fine and myself to you regarding the opioid prescribing guidelines. I have also attached an op-ed which will appear in the journal of Pain Medicine in about 4-6 weeks and the AAPM response to the Washington State opioid prescribing guidelines that was previously published.

I hope you will find these comments useful in your deliberations and leadership of managing a difficult problem for our state.

Lynn Webster, M.D.
Board Certified in Anesthesiology
Board Certified in Pain Medicine
Certified in Addiction Medicine

November 11, 2008

Robert Rolfs, MD
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Dear Dr. Rolfs,

We have reviewed the most recent draft of the Utah Clinical Guidelines on Prescribing Opioids and feel they reflect the hard work and productive collaborations that have gone into drafting them. Many improvements have been made during the development process, but problems remain that could cause needless difficulty for patients and providers.

Of paramount importance, recommendation 7.2 looks unchanged in reference to the 120 mg dose at which specialist consultation is recommended. This guideline, which is based on a similar guideline adopted in Washington State, is drawing opposition from professional medical societies, including the American Academy of Pain Medicine (AAPM), the American Pain Society, and the National Pain Foundation. Scott Fishman, MD, former president of AAPM, has co-authored an editorial on the subject of the Washington state guideline that is to appear in an upcoming issue of Pain Medicine journal. We enclose a copy of this editorial along with a position letter from the AAPM. Please take time to consider the brewing controversy over the 120 mg ceiling and avoid perpetuating more problems associated with it.

Still another recommendation (2.1) also threatens inadvertent harm to patient care by unduly circumscribing physician decision making. The descriptive paragraph under the recommendation says, in essence, that chronic non-cancer pain patients should have to fail non-opioid treatments before being given a trial of opioids. It is not medically sound to insist that clinicians try "NSAIDs, antidepressants," etc, "first" before a trial of opioids can be initiated, regardless of the medical condition. This oversteps the recommendation's purpose. Obviously, if the magnitude of pain can be adequately managed with a non-opioid therapy, it should be tried. But a patient who presents with severe pain will needlessly suffer if forced to undergo all conservative options before being started on an opioid. The last sentence "Opioid therapy should be considered only … have not proven beneficial" should be deleted or revised. The whole paragraph should be rewritten to reflect that these alternative treatments for chronic pain exist, may be appropriate, and should be considered. But nowhere should be it stated or implied that all patients with any form of chronic pain must "fail" these treatments first. As written, we would prefer not to see this paragraph end up in the final guideline.

See also recommendation 5.4. Some confusion has been introduced into the guideline between "treatment plans" and "treatment agreements or contracts." A treatment plan contains therapeutic goals, but a treatment agreement is focused on preventing misuse and diversion. Treatment plans are written in terms of medical records and documentation, but the treatment agreement is signed by both patient and physician. See, for example, under recommendation 5.4 when a discussion about patient driving becomes muddled in this regard. Later, under recommendation 11, it becomes a little clearer that the "treatment plan" refers to medical records and documentation.

We are unclear whether or not margin comments are likely to be adopted, but we would recommend against inserting non-clinical language such as "chronic lifetime narcotics" into the guideline. We would also warn that it should not be feared as a loophole likely to "feed the beast" of addiction to raise or otherwise adjust doses to counteract tolerance or

to treat a worsening pain condition. The guidelines provided for appropriate monitoring and expert consultation are precisely the tools needed to guard against this possibility.

In the document's introduction, we take issue with simply stating that no evidence exists that opioids for chronic pain have long-term benefit. The following reference is one such piece of recent evidence: Noble J Pain Symptom Manage 2008;35(2):214-28.

Several recommendations have been much improved. For example, recommendation 6.3 now has a sentence added that clarifies it is not meant to discourage intrathecal treatment. Also, the recommendation to check the CSDB at least annually appears to be a more reasonable and clinically workable requirement than the last time we saw this document.

The legislature's intent was that the guidelines be supported by the various medical stakeholders, whom we are sure you would agree would include those of us most involved in pain management. Unfortunately these guidelines fail to meet the minimum level of acceptance for us and, we are sure, by others in our field. We urge you to you to revise these guidelines to be consistent with the science of opioid prescribing and recommendations by the AAPM and APS.

The Utah Department of Health has demonstrated national leadership in addressing the crisis of unintentional overdose deaths. We have appreciated the opportunity to work with you on this important community problem.

Sincerely,

Lynn Webster, MD
Perry Fine MD

cc: Erin Johnson
Kim Bateman, MD
David Sundwall, MD
Alan Colledge, MD

Unintended Harm from Opioid Prescribing Guidelines

There's a new front in the ongoing battle to preserve access to pain relief, and a Trojan Horse is nestled inside a measure intended to protect patients from harm. It takes the form of a guideline drafted by the Washington State Agency Medical Directors Group (AMDG) (1) to assist with opioid dosing for chronic non-cancer pain. The main stated goal of the AMDG is to reverse the trend of accidental deaths associated with prescription opioids. The goal is worthy, but the guideline is misguided. The AMDG suggests that doses above 120 mg oral morphine equivalents per day should rarely be given and "only after pain management consultation." There are a number of reasons why this arbitrary ceiling dose is not a solution and could hurt patient care, particularly if this state guideline spurs a national trend.

At the heart of the problem is the failure of the guideline to recognize that the supply of specialists is as limited in Washington state as elsewhere throughout the United States. Indeed, the guideline does not even define what is meant by a "pain management specialist." Even one of the guideline's drafters questions whether the plan is workable: "The problem right off the bat is there must be 15,000 people in the state who are over 120 milligrams. Where are the pain specialists going to come from?" asked John Loeser, M.D., former president of the American Pain Society and International Association for the Study of Pain (2). The question remains unanswered, and the state is facing a lawsuit that alleges flawed data and the limiting of access connected to the guideline (2).

It is remarkable that the 120 mg guideline was confirmed without access to sufficient scientific evidence. Nowhere is it shown that the recommendation contributes to greater safety or diminished harm. Furthermore, it specifies a diagnosis of "non-cancer pain," thus setting up possible discrimination against patients without a cancer diagnosis. And it uses the non-clinical term "drug-seeking behavior" that lacks definition or criteria and perpetuates stigma.

Another unintended negative consequence is the false suggestion that daily doses below 120 mg are inherently "safe." One must ask why apply great vigilance only at relatively high doses. If a patient in the presumed "safe" range were to have complicating conditions such as sleep apnea or were taking concomitant benzodiazepines, for example, he or she could receive less clinical vigilance than needed. Methadone is a prime example of a medication that always requires close monitoring. A starting dosing regimen of 10 mg of methadone four times per day, as allowed by most conversion tables, would fall below the 120 mg morphine equivalent level yet, unfortunately, this amount of methadone has been fatal in some instances. The AMDG guideline misses its target from the outset. A far more medically sound goal would be to focus on how to educate physicians to appropriately prescribe and monitor patients on all levels of opioids, not just higher doses.

The guideline sends other erroneous messages as well. It assumes that the very real problems of opioid misuse, diversion, and overdose death must be caused mainly by physician error and, therefore, can be solved by specialist intercession. It further suggests that all pain specialists actually know how to prescribe opioids. In fact, some evidence shows that specialists and non-specialists share a similar rate of unintentional overdose deaths among patients (3).

How will this guideline impact legitimate care to pain patients throughout the country? It is possible its influence could spread if it comes to be seen as a precedent. For the past year, the Utah Department of Health has convened stakeholders to develop opioid prescribing guidelines, and some are pushing to suggest pain management consultation at the daily 120 mg ceiling dose in imitation of the AMDG. As in Washington state, it would be impossible for all Utah patients at or above that opioid level to be seen by pain

specialists. The impact could be an arbitrary dose limitation regardless of patient need. If other states follow suit, many patients could suffer needlessly.

If the dose limit were widely adopted, physicians could carry additional burdens. More physicians and other prescribing clinicians are likely to simply reduce their opioid prescribing rather than risk increased scrutiny under a system in which the rules are untested and the potential penalties unclear. Sadly, the widespread acceptance of such questionable policy could lead to more untreated pain, increased incentive for doctor shopping, and diversion.

All this highlights a disturbing trend in the development of regulatory policy concerning opioid prescribing: First an outcry goes up to encourage practitioner engagement in the solving of a newly identified public health crisis. Next, clinicians, who were never properly educated to optimally treat the condition, accept the call to help resolve the public health crisis. When problems in the ensuing care arise, regulators act to stop further problems, often without concern for the collateral impact on appropriate care for legitimate patients. The planning for education and training to address the problem is absent, and care is discouraged whether intentionally or not.

This is why medical guidelines should be drafted only in consult with relevant and responsible professional organizations. Unfortunately, the lack of such collaboration leads to processes that appear needlessly adversarial. In regard to the Washington state guideline, no major pain group has supported it. The AAPM has taken a formal position opposing the guideline (4) as have the American Pain Foundation (5), the American Pain Society (6), and other pain-related organizations. In sum:

> "AAPM shares major concern about the serious public health crisis of prescription drug abuse that stimulated development of these guidelines. However, we believe that the solution to this public health crisis must involve education of physicians and medical trainees on safe and effective opioid prescribing practices, not in enacting policy which further restricts the prescribing of opioids (4)."

Policies, laws, and guidelines should focus on raising skill and awareness, not fear. They should address core problems and effect positive change. Part of that comes from accepting realities, among them that pain is treated in primary care settings and that funding is necessary to enact mandates. Positive change includes providing positive tools, such as screening and assessment for pain patients, guides to monitoring treatment, and prescription monitoring programs that work at the point of care. To enact positive policy, the right questions must be asked and answered. Why not focus on methadone, which is associated with a disproportionate amount of harm regardless of the dose? Is cost of higher doses of brand-name opioids an underlying concern? If so, be transparent and use guidelines to help address cost and safety issues rather than disguise this intent of the 120 mg dose limit.

No one questions the value of working to eliminate the devastation of opioid misuse and overdose death. The problem is real, but the AMDG guideline is not a solution. It is inadequate policy for the sake of action. Every respected national pain organization opposes this restriction, and it has no real substantive support outside Washington state. Reasonable policymakers in any state should be dissuaded from adopting this type of policy.

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References

1. Interagency guideline on opioid dosing for chronic non-cancer pain: an educational pilot to improve care and safety with opioid treatment. Published by Washington State Agency Medical Directors' Group, March 2007.

2. Byron L. Investigators: Accidental overdoses on the rise. King 5 News. October 6, 2008. Retrieved October 30, 2008 from http://www.nwcn.com/health/stories/NW_100608INV_overdose_KS.de4ef8bb.html#.

3. Porucznik C. Update on prescription drug overdose research. University of Utah School of Medicine, Public Health Program & Utah Department of Health. Retrieved November 5, 2008 from http://health.utah.gov/prescription/pdf/steering_com_pdf/ResearchUpdateApril.pdf.

4. AAPM position on the Washington State Agency Medical Directors Group (AMDG) published guidelines on opioid dosing for chronic non-cancer pain. October 16, 2007.

5. American Pain Foundation (2007, May). APF position statement on Washington State interagency guideline on opioid dosing for chronic non-cancer pain: An educational pilot to improve care and safety with opioid treatment. Retrieved January 4, 2008, from http://www.painfoundation.org/PositionStatements/WAOpioidGuideline2007.pdf.

6. Paice, J. A. Letter from president of American Pain Society to Washington State Agency Medical Directors Group. July 19, 2007. Retrieved January 4, 2008, from http://www.ampainsoc.org/enews/aug07/APSBoardResponse.htm.

October 16, 2007

AAPM Position On The Washington State Agency Medical Directors Group (AMDG) Published Guidelines On Opioid Dosing For Chronic Non-Cancer Pain

The American Academy of Pain Medicine (AAPM) represents physicians in the specialty of Pain Medicine. AAPM opposes The Washington State Agency Medical Directors Group published guidelines on Opioid Dosing for Chronic Non-Cancer Pain and stands in agreement with the public positions of the American Pain Society and the American Pain Foundation. AAPM shares major concern about the serious public health crisis of prescription drug abuse that stimulated development of these guidelines. However, we believe that the solution to this public health crisis must involve education of physicians and medical trainees on safe and effective opioid prescribing practices, not in enacting policy which further restricts the prescribing of opioids. Recognition of adverse effects of opioids, including over-dosage, drug abuse and diversion, must receive serious action. Likewise, the well documented public health crisis of under-treated pain must also be addressed.

Despite well-intentioned efforts to address prescription drug abuse, the AAPM believes that by enacting the Washington State AMDG published guidelines on Opioid Dosing for Chronic Non-Cancer Pain there is a likely potential for increasing the existing under treatment of chronic pain. Although specialty consultation may be helpful for many patients in pain, a state level recommendation for such a consultation, without a plan for ample access to appropriate specialists or reimbursement for such consultation for the majority of patients who might require such care, will only lead to reluctance for physicians to treat chronic pain, and greater suffering for legitimate patients in pain. The core problem with the AMDG guidelines is that many physicians may be unable to obtain the required consultations and will fear that if they do not follow the guideline they will be viewed as practicing beneath the standard of care. Such a provocative message from the state government without clearly defined and ample resources for implementation will negatively impact the willingness of physicians to treat pain. As a result, legitimate patients who deserve and would otherwise receive appropriate dosing with opioids may be left with increasing obstacles to care. The AAPM cannot support the WA state guidelines until the state can clarify how the required consultations will be made available and funded. Other major concerns about the Washington State AMDG Opioid Dosing Guidelines include:

- Lack of scientific evidence supporting any positive outcomes such as safety or diminished harm
- Flaws in the one retrospective study (Franklin et al, 2005) upon which the guidelines are primarily based
- Unintended consequences including restrictions and additional barriers to patients who experience pain
- Potential discrimination against patients in pain without a cancer diagnosis
- Lack of definition of, or criteria for, a pain specialist
- Lack of definition of or criteria for terms such as "drug-seeking behavior" which pose great potential for inappropriate and discriminatory application

AAPM believes that efforts to improve the two public health problems of prescription drug abuse and under-treated pain must include education on effective and responsible use of controlled substances for medical students and physicians at all levels. Educating our physicians may well help to obviate the need for restrictive policies such as the Washington State AMDG Guidelines on Opioid Dosing for Chronic Non-cancer Pain.

NWCN.Com NW News and Weather
http://www.nwcn.com/health/stories/NW_100608INV_overdose_KS.de4ef8bb.html#

Investigators: Accidental overdoses on the rise

11:11 PM PDT on Monday, October 6, 2008

By LINDA BYRON / KING 5 News

SEATTLE - People usually associate drug overdoses with cocaine or heroin users, but there's another kind of overdose that can happen to anyone. It's when people accidentally overdose on prescription drugs and it's being called an epidemic here in Washington state.

It happened to 32-year-old Angie Burrell of Renton in February. Her mother, Sara Taylor, is still trying to figure out what went wrong. As she empties out a garbage bag full of leftover pill bottles, Taylor tells us that Angie spent most of her final day alone in her bedroom.

"And we went up to check on her and she was dead," Taylor said. "She looked like she was trying to get out of bed."

Angie had been battling chronic pain ever since undergoing surgery three years earlier. Medical records obtained by the KING 5 Investigators list 17 current prescriptions in her chart two days before her death. The King County Medical Examiner ruled that four of those drugs combined killed her.

The KING 5 Investigators asked Sarah Taylor: "Do you think she understood the dangers?" Taylor said: "No, I think she did not. I don't think she did."

The two most potent drugs in Angie's system were methadone and oxycodone. Both are opioids, narcotic pain killers considered so powerful and potentially addictive they were once limited to patients dealing with severe medical conditions, like surgery or cancer.

But in the mid-1990s, Washington and other states began encouraging the expanded use of prescription opioids for everything from backaches to headaches. It wasn't long before people started accidentally overdosing and dying.

"Washington State, similar to seven or eight other states, are in the highest ranges of death rates in the country," said Dr. Gary Franklin, Medical Director for the Washington State Department of Labor & Industries. "None of this is acceptable."

Franklin was one of the first people nationwide to sound the alarm. He identified 32 injured state workers who had apparently overdosed.

"I haven't seen too much, anything really, sadder than a worker coming into the system with a low backache and then dying four years later from an accidental overdose of prescription opioids," Franklin said.

The KING 5 Investigators analyzed data from law enforcement agencies and health departments to see how big the problem is in Washington. We found unintentional prescription overdoses have increased 17 times in little more than a decade.

Accidental poisonings, primarily overdoses, now kill more people than car accidents.

Prescription drugs containing opioids do help some people, especially people with chronic pain. But there's a big debate over how much is safe.

"We also know that people often don't get better on high dose narcotics," said Professor John Loeser, former director of the University of Washington Pain Center. "What worries the pain world the most is the patient who takes just what I told them to take, who dies from it," Loeser said.

That's why **Loeser joined Dr. Franklin and other medical directors in writing state guidelines, including an opioid dose calculator, which measures the morphine equivalents of various drug combinations.**

The guidelines say the patient should see a pain specialist when the total hits 120 milligrams. It's good in theory, but even Loeser questions whether it's really workable.

"The problem right off the bat is there must be 15,000 people in the state who are over 120 milligrams," Loeser said. "Where are the pain specialists going to come from?"

The state is being sued by a doctor and group of patients who claim the recommended doses are based on flawed data and could lead to the under-treatment of chronic pain.

At the time of her death, Angie Burrell's morphine equivalent dose was more than twice the red flag dose - roughly 300 milligrams.

Sarah Taylor wants some answers.

"I don't know where to turn to," she said.

From looking at Angie's chart notes, we do know the doctor was concerned about the risk of combining powerful drugs.

Just two days before she overdosed, the doctor warned Angie not to take prescribed drugs for insomnia and anxiety too close together. They could cause her to stop breathing. Ironically, neither of those drugs was listed on her death certificate. It was four other drugs that killed her.

"This just should never have happened," Taylor said. "It should never have happened."

So why did it happen? Was Angie taking her medications as prescribed or did she overdo it? We couldn't get that answer from either the King County Medical Examiner or the University of Washington, where she was being treated. But a medical team is reviewing Angie's case and promises to meet with the family this month.

There is no exact formula for what's safe. That's what the state guidelines are trying to determine. But experts say people should be very wary of combining painkillers containing opioids with other depressants, including anti-anxiety medications or sleeping pills. The combination can be very dangerous.

Because of the pending lawsuit over the opioid dosing guidelines, Washington State's health department put its widespread educational campaign for doctors on hold.

It's considered a landmark case for the rest of the country.

Edward B. Holmes
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David and Jim,
I wanted to keep you in the loop on the opiate treatment guidelines. At the advisory council meeting, the commissioner asked Dr. Rolfs to coordinate with me and others to get some of the work comp needs incorporated. Dr. Rolfs has not yet contacted me directly for input but
I did note the guidelines were published on their website for public comment and was notified of such. Dr. Colledge asked me to comment on them. I will copy these comments to the health department. I admit to being strongly in one camp on this issue and am not afraid to admit it.
In short, I think that the human cost in lives lost, lifestyle lost, family life lost, work years lost, productivity, medical expenses, etc is simply too great to ignore any longer in our community and society. These medications are extremely dangerous and addictive yet given out
freely to young people, teenagers with toothaches, young adults, and injured workers with temporary conditions, etc. Many go on to a lifetime of addiction and disability. I think prescribing practices should be stringently regulated for overall public health purposes. I think a strict guideline is a good start. However, a weak guideline will in some ways lead to "justified" continuance of that standard practice of freely prescribing.

Attached below is a Word document. I did not edit the entire guideline but instead offered some comments regarding concepts, highlighted in red with "track changes", which begin at about printed page 7 "Summary of Recommendations". I think these types of changes that I noted in the summary for each chapter need to be incorporated into each of the chapters/sections below with the same numbered heading. Please review at this time during the public comment period and contact your constituencies that may have an interest in this issue to comment.

Thank you

PS Thank you Dr. Rolfs and Health department staff for working hard to begin this process of improving opiate prescribing practices in Utah

Ed

Summary of Recommendations

Opioid Treatment for Acute Pain
1) Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after ~~consideration~~ unsuccessful use of other non-opioid pain medications and therapies.
2) When opioid medications are prescribed for treatment of acute pain, the number dispensed should be no more than the number of doses needed based on usual duration of pain for that condition.
3) When opioid medications are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely, not share with others, and to dispose of properly when the pain has resolved to avoid use of the medications for non-medical purposes.
4) Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where adequate monitoring and assessment for adverse effects can be conducted.
5) The use of opioids should be reevaluated if persistence of pain suggests the need to continue opioids beyond the anticipated time period for acute pain treatment.

Opioid Treatment for Chronic Pain
1) A comprehensive evaluation should be conducted before initiating opioid treatment.
2) ~~Consideration should be given to~~ alternatives to opioid treatment, including adequate therapeutic trials, should be conducted before initiating opioid treatment.
3) The provider should consider and screen for risk of abuse or addiction before initiating opioid treatment.
4) A consultation and second opinion on the necessity for chronic (likely life long) opioid therapy shall be obtained prior to initiating such therapy.
A treatment plan should be established that includes measurable goals for reduction of pain and improvement of function[1] with continued opioid treatment contingent upon documented functional improvement.
5) The patient should be informed of the risks and benefits and any conditions for continuation of opioid treatment, ideally in a written and signed treatment contract and plan to include risks of abuse, addiction, diversion, theft, and death (especially including young people and teenagers since they feel immortal).
6) Opioid treatment for chronic pain should be initiated as a treatment trial, usually using short-acting opioid medications.

[1] "Function" as used here is defined broadly to include emotional, cognitive, and psychological function.

7) Regular visits with evaluation of progress against goals should be scheduled during the period when the dose of opioids is being adjusted (titration period).
8) Once a stable dose has been established (maintenance period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored.
9) Continuing opioid treatment after the treatment trial should be a deliberate decision that considers the risks and benefits of chronic opioid treatment for that patient and should be based upon proof of effectiveness by objective measures of improved functioning and activity. A second opinion or consult may be useful in making that decision
10) An opioid treatment trial should be discontinued if the goals are not met and opioid treatment should be discontinued at any point if adverse effects outweigh benefits or if dangerous or illegal behaviors are demonstrated.
11) Clinicians treating patients with opioids for chronic pain should maintain records documenting the evaluation of the patient, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed.
12) Clinicians should consider consultation for patients with complex pain conditions, patients with serious co-morbidities including mental illness, patients who have a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her abilities to manage the treatment.
13) Methadone should only be prescribed by clinicians who are familiar with its risks and appropriate use due to the significant risk of sudden death.

Alan Colledge
drcolledge@msn.com

Concern with Pain Guidelines 11 17 08

Larry,

Dr. Holmes observations are consistent with mine.

I will be meeting with the Pain Guidelines Guidance Committee tomorrow at 9 am at the Health Department.

I believe we must get recommendation 9.2 moved up and placed before 6.1 for
these to be of value to the Labor Commission.

I recommend this because narcotics are not benign medications. We are not beginning a trial of an anti-inflammatory or muscle relaxer, of which stopping the drug is simplistic. The narcotic medications we are giving patients are extremely addictive and life changing. Often once they begin to take these medicines they can develop significant secondary effects of hyperalgesia, depression, and with a lack of initiative. All these effects are extremely counterproductive for injured workers trying to get back to employment.

These guidelines as they are currently written allow for the increasing of the narcotics until some nebulous endpoint is obtained, of either where the patient does not want any more or where the doctor gets uncomfortable prescribing them.

After that point it becomes very difficult for anyone to convince the patient that they should be taken off the narcotics in that the patient experiences withdrawal symptoms with an escalation of pain. (That is why individuals who are addicted donÆt simply stop their narcotic use themselves.)

Unfortunately, after taking narcotics, many of the patients become ôhardwiredö for these drugs and from that point on are never the same. Their problem of pain and narcotics has now has become far bigger than the original industrial sprain and strain, with their life now involved with significant physical addictive issues and psychosocial problems.

Dr. Holmes, Dr. Stewart and I have simply recommended that before a physician or a physician extender start someone on chronic lifetime narcotic use, that a request for a second opinion is btained by a peer.

Often a peer will have ideas to try other than narcotics. It is not unusual for the patient really wanting to be rescued from the primary doctor in that they are receiving no benefit. When the realities of lifelong narcotic use are presented to the patient, often they or their family members desire to try other interventions.

In summary, although there are many good things in these guidelines, I really do not believe a trial should be given without a peer consult. As Dr. Holmes has expressed, without this in the guidelines I think we are only giving a green light for narcotic escalation based upon subjective complaint of pain. These guidelines will then facilitate the issue of chronic pain becoming even more problematic to the labor commission. I would like to know your thoughts.

Dr. Holmes and I will be in the office tomorrow morning at 11:30 and would like to discuss this with you after our meeting with the Guidance Committee.

Initiating, Monitoring, and Discontinuing Opioid Treatment:

6. Initiate trial of opioid therapy
6.1 Recommendation: Opioid medication should be initiated as a short-term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life.

9.2 Recommendation: A second opinion or consult may be useful in making the decision to continue or discontinue the opioid treatment trial.

Kimberly Phillips, APRN
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As a healthcare practitioner who was duped by a very clever addict, I have some very specific thoughts on how this legislation can protect not only the public but prescribers as well. It is my general belief that very few practitioners set out to prescribe irresponsibly or enable addiction. Yes, there are those who have serious issues themselves and misuse the trust that has been placed in them but by and in large we should assume good intent.

- It is my belief that Utah should continue to require a state controlled substances license as well as a federal DEA registration in order to prescribe to patients.
- It is my belief that C-2 drugs should not be included in a general controlled substances license and that a special license should be granted to only the following professionals:

  Certified Pain Management Practitioners
  Anesthesiologists/Anesthetists
  Surgeons (may write for up to 4 weeks after surgery) then a referral must be made to Chronic Pain Management Specialist
  Oncologists

- It is my belief that all Utah prescribers should be trained, certified and authorized to prescribe addiction medications such as soboxone
- It is my belief that ALL narcotic tablets should have a bubble of naloxone embedded in them so that if they are crushed, dissolved or in anyway compromised that the narcotic becomes useless. It is my belief that for those persons who have feeding tubes etc that require a liquid form of medication that only pharmacy compounds be prescribed.
- It is my belief that all prescriptions for controlled substances should be electronically submitted and that practitioners should be required to submit 100% of the controlled substances they write for to either the DEA or DOPL on a random basis to ensure that inappropriate prescribing practices are not occurring
- It is my belief that there should be a ZERO tolerance for telephone orders for any and all controlled substances
- It is my belief that it should be considered unprofessional conduct to utilize signature stamps for prescriptions
- It is my belief that ALL prescriptions should be submitted electronically by 2010. There should be no reason for a hand written prescription to be given to a patient.
- It is my belief that DEA numbers should not be written on prescriptions but that pharmacies should call to verify the DEA number on controlled substances. The NPI number is an adequate ID number to verify a prescriber

****

It is my belief that all patients receiving narcotics must sign a legally binding contract with their practitioner that:

- Limits them to ONE pharmacy
- Requires that the person picking up the prescription submit picture ID that is scanned into the patient record and checked by the pharmacy staff with each and every refill of a controlled substance.
- A DOPL report must be run on every patient each month
- Random drug urine drug screenings
- Agree that any breech of the contract by the patient is grounds for dismissal from the practice of practitioner and releases them from any obligation to prescribe for the patient and any harm.

I also wanted to add this ...

The CSDB (Controlled Substance Database) *MUST be updated to real time*.
The delay of weeks is unacceptable. Right now pharmacies can be up to 30 days behind in submitting controlled substances prescriptions to the CSDB. This creates problems because even if you check a DOPL/CSDB report on a patient, it may not be up to date and the missing information may change your decision on whether or not to prescribe.

For example, by the time I ever received any kind of notification from the CSDB on the patient that used me it was a month after I had turned myself in (because I ran a DOPL) and found > 15 prescribers in 120 days. As I stated before, giving practitioners *ALL* the tools they need to combat this sort of thing is key to stopping irresponsible prescribing and harm to the public.

Howard Leaman, MD
howard.leaman@imail.org

ALSO SEE THE E-MAIL FOR A WORD DOCUMENT THAT WOULD NOT COPY OVER……

Greetings,
I've attached your document with several items marked in "Track Changes" which relate to sleep apnea.

Items:
1.2 Assess for risk of OSA using Berlin questionnaire a validated method (article attached)

12. (It's not just Methadone: Include OSA and other medications in your risk profile for opioid adminstration, potential for drug-drug interaction. This is particularly true in smaller individuals where dose per unit weight is significant. (see slide)

13. Methadone: same suggestions as in 12.

Please be aware that sleep related respiratory difficulties are not associated only with typical or obvious OSA risk patients. All factors affecting vulnerability to respiratory depression are currently unknown, however be aware that many of the patients dying, and the largest increases in death with opiates were in the low BMI patients, suggesting that dose per unit mass is a significant risk.

References: added Berlin questionnaire, Scientific articles by our laboratory on central sleep apnea and opiates.

Please take a look at the modifications and let us know if you would like more on sleep apnea recognition besides the Berlin questionnaire.
thanks

Pain Medicine
Grand Rounds
Sleep Disorders

Howard M. Leaman, MD

Presented at

on

January 26, 2007

Intermountain Healthcare

Increase in Utah Poisoning Deaths by Non-illicit drugs 1991-2003

M. Caravati MMWR Jan 2005

- Methadone 2➔33/yr
  - (50% taking prescribed methadone for the first time)
- Other prescription narcotics 10➔48/yr
  - (Oxy/Hydrocodone)
- Age 25-54, Male>Female, Urban>Rural

- More likely to die if you're Obese,
- But
- Patients with normal BMI had largest increase in death rate

TABLE 1. Number* and rate† of deaths from non-illicit drug poisoning of unintentional or undetermined intent, by selected characteristics — Utah, 1991–1998 and 1999–2003

Characteristic	No. of deaths 1991–1998 No.	(%)	1999–2003 No.	(%)	Difference	Death rate 1991–1998	1999–2003	% change in death rate
BMI§								
<25.0	65	(31)	130	(27)	65	1.17	3.61	208
25.0–29.9	65	(31)	143	(30)	78	1.90	5.26	177
≥30.0	81	(38)	207	(43)	126	6.06	14.25	135

* N = 733.
† Per 100,000 population.
§ Body mass index (kg/m²).

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Using the Berlin Questionnaire To Identify Patients at Risk for the Sleep Apnea Syndrome

Nikolaus C. Netzer, MD; Riccardo A. Stoohs, MD; Cordula M. Netzer; Kathryn Clark; and Kingman P. Strohl, MD

Background: Although sleep apnea is common, it often goes undiagnosed in primary care encounters.

Objective: To test the Berlin Questionnaire as a means of identifying patients with sleep apnea.

Design: Survey followed by portable, unattended sleep studies in a subset of patients.

Setting: Five primary care sites in Cleveland, Ohio.

Patients: 744 adults (of 1008 surveyed [74%]), of whom 100 underwent sleep studies.

Measurements: Survey items addressed the presence and frequency of snoring behavior, waketime sleepiness or fatigue, and history of obesity or hypertension. Patients with persistent and frequent symptoms in any two of these three domains were considered to be at high risk for sleep apnea. Portable sleep monitoring was conducted to measure the number of respiratory events per hour in bed (respiratory disturbance index [RDI]).

Results: Questions about symptoms demonstrated internal consistency (Cronbach correlations, 0.86 to 0.92). Of the 744 respondents, 279 (37.5%) were in a high-risk group that was defined a priori. For the 100 patients who underwent sleep studies, risk grouping was useful in prediction of the RDI. For example, being in the high-risk group predicted an RDI greater than 5 with a sensitivity of 0.86, a specificity of 0.77, a positive predictive value of 0.89, and a likelihood ratio of 3.79.

Conclusion: The Berlin Questionnaire provides a means of identifying patients who are likely to have sleep apnea.

The obstructive sleep apnea–hypopnea syndrome is a potentially disabling condition characterized by excessive daytime sleepiness, disruptive snoring, repeated episodes of upper airway obstruction during sleep, and nocturnal hypoxemia. Epidemiologic surveys indicate associations among snoring, sleep apnea, and cardiovascular disease (1). A 1993 population-based study (2) of workers in Wisconsin found that 2% of women and 4% of men had symptoms of sleepiness with associated levels of sleep apnea believed to indicate at least a moderate degree of illness. Prevalence estimates from other countries and other U.S. studies are similar (3–5). Recognition of sleep apnea by community physicians is, however, low. In the Wisconsin study (6), only 7% of women and 12% of men who had moderate to severe illness reported receiving a diagnosis of sleep apnea from a medical encounter.

Two studies observed that specialist intervention with diagnostic equipment (7) or intensive physician education on taking a sleep history (8) improved recognition of sleep apnea in primary care practices. However, both approaches required substantial professional and technical resources. Asking patients to report their symptoms is a simple alternate approach that has been shown to be helpful in sleep referral clinics and community surveys (1).

The Berlin Questionnaire asks about risk factors for sleep apnea, namely snoring behavior, waketime sleepiness or fatigue, and the presence of obesity or hypertension. We evaluated the usefulness of this instrument in identifying patients with sleep apnea in primary care settings.

See editorial comment on pp 535-536.

Ann Intern Med. 1999;131:485-491.

For author affiliations and current addresses, see end of text.

Methods

The Berlin Questionnaire

The Berlin Questionnaire was an outcome of the Conference on Sleep in Primary Care, which involved 120 U.S. and German pulmonary and primary care physicians and was held in April 1996 in Berlin, Germany. Questions were selected from the literature to elicit factors or behaviors that, across studies, consistently predicted the presence of sleep-disordered breathing (1, 9–15). By consensus, the instrument focused on a limited set of known risk factors for sleep apnea. One introductory question and four follow-up questions concern snoring; three questions address daytime sleepiness, with a sub-question about sleepiness behind the wheel (that is, while driving a motor vehicle). One question concerns history of high blood pressure. Patients are also asked to provide information on age, weight, height, sex, neck circumference, and ethnicity. Obesity was quantified by calculating body mass index from self-reported weight and height. The responses to these questions have utility in non–primary care settings (1).

The conference also proposed a plan for risk grouping to simplify recognition of sleep apnea; this strategy was shown to be useful in sleep clinic and community surveys (11, 13, 15). Predetermination of high risk and lower risk for sleep apnea was based on responses in three symptom categories. In category 1, high risk was defined as persistent symptoms (□3 to 4 times/wk) in two or more questions about their snoring. In category 2, high risk was defined as persistent (□3 to 4 times/wk) waketime sleepiness, drowsy driving, or both. In category 3, high risk was defined as a history of high blood pressure or a body mass index more than 30 kg/m^2. To be considered at high risk for sleep apnea, a patient had to qualify for at least two symptom categories. Those who denied having persistent symptoms or who qualified for only one symptom category were placed in the lower risk group.

Survey Distribution

One thousand questionnaires in batches of 200 per study site were provided to individual physicians at five sites in the Cleveland, Ohio, area. The sites were chosen on the basis of geographic and socioeconomic diversity (further information is available from the authors on request). Three physicians were solo practitioners and 2 were members of a practice group; all practices were part of a hospital-owned network that at the time of study included 92 primary care physicians who cared for adults. All 5 participating physicians were Board-certified in internal medicine, and 2 had more advanced training (rheumatology or pulmonary medicine). By design, all participating physicians had practiced primary care medicine for more than 4 years and had stable practice patterns, each handling a panel of 2500 to 3000 patients. According to network records, no physician had referred more than 2 patients for sleep studies in the previous year.

Office staff handed out questionnaires to consecutive patients who visited the study physician for any reason. Each site was instructed to return the questionnaires to the sleep center. Completed questionnaires were included in our analysis if they met the following criteria: They had to be dated, the date had to fall within 3 weeks of distribution, and they had to be returned to the sleep center within 1 month. The study was approved by the institutional review board of University Hospitals of Cleveland.

Sleep Studies

Portable monitoring of respiratory disturbances during sleep was offered to both high-risk and lower-risk patients. The intent was to study approximately 20% of respondents, equally distributed in both risk groups. From an alphabetically ordered list, the first 75 patients in the high-risk group and the first 65 patients in the lower-risk group were contacted by telephone and asked to participate. Patients who agreed to sleep studies were visited at home, instructed on the use of the monitor, and monitored overnight; the monitor was retrieved the next day. Patients gave written consent for portable monitoring and for results to be sent to their primary care physician.

Monitoring was performed with a six-variable, four-channel Eden Tec recorder (Nellcor Puritan Bennett, Minneapolis, Minnesota). Variables measured included nasal and oral airflow by thermistor, chest wall movement by impedance electrodes, and oxygen saturation (SaO_2) and pulse rate by pulse oximeter. A respiratory disturbance event was defined as a decrease in nasal or oral airflow, alone or with chest wall movement of approximately 50% that lasted for 10 seconds or more. A decrease in SaO_2 of 4% or more was considered significant oxygen desaturation. The recorder was taken to the patient's home, where he or she was instructed on how to use the recording device and to turn it on at bedtime and to turn it off upon arising (13). Measurements from a full-disclosure printout were manually scored for a respiratory disturbance index (RDI) (measured as the number of respiratory events per hour in bed) and the oxygen desaturation index (number of decreases in SaO_2 of □ 4% per hour in bed). Acceptable records were those in which the patients spent at least 6 hours in bed and good

to excellent recording of Sa_{O_2} and respiration (either impedance or thermistor records or both) was achieved (13). A single researcher who had no knowledge of the questionnaire results performed the scoring.

Statistical Analysis

The quantitative distribution of returned questionnaires, individual patient variables, responses to individual questions about sleep-related symptoms, and results of home sleep monitoring are expressed by descriptive statistics (frequencies, mean □ SD, and range). Missing data and data that are not applicable are expressed in the percentage of the returned questionnaires and in total number of patients for each variable. Answers to questions on sex and study site were evaluated by using the chi-square test and were expressed by the significance level. The Pearson correlation test and level of significance were used to compare questionnaire responses and risk groupings. We used a logistic regression model that examined the relative effects of age, sex, and the three symptom categories and risk group. The predictive accuracy (16) of risk grouping and of each category was assessed for RDIs of 5 or less, more than 5, more than 15, and more than 30; these arbitrary cut-off values are similar to those used in previous studies (2, 6) and those proposed as diagnostic criteria (17). Computations were performed by using SPSS 7.5 for Windows (SPSS, Inc., Chicago, Illinois).

Results

Of 1008 questionnaires (one physician had distributed an additional 8 questionnaires), 744 (74%) were entered for analysis. The variability in return rate resulted from time constraints and unavailability of staff rather than patient refusal. The return rate did not correlate with the socioeconomic profile of the practice site; solo practices had greater response rates. One male respondent and one female respondent reported that they had received a diagnosis of or treatment for sleep apnea; their results were included in the analysis.

Characteristics of the respondents are shown in Table 1. Because responses to the questions on neck circumference and ethnicity were often not provided, these results were not included in the analyses.

Prevalence of Symptoms

Of the 744 respondents, 388 (52.2%) reported that they snored, 223 (30.0%) denied snoring, 118 (15.9%) did not know whether they snored, and 15 (2%) did not respond to this question. Ninety-four of all respondents (24.6%) reported that their snoring was louder than normal speech and 289 (75.4%) did not snore louder than normal speech. Two hun-

Table 1. Self-Reported Characteristics of the 744 Survey Respondents*

Characteristic	Data

Mean age □ SD, y 48.9 □ 17.5
Sex, n (%) Male 310 (41.7) Female 403 (54.2) Not reported 31 (4.2)
Body mass index, n (%)
□30 kg/m^2 370 (49.7)
□30 kg/m^2 276 (37.1)

Not reported 98 (13.2) Mean body mass index □ SD, kg/m^2 29 □ 7.2
High blood pressure, n (%)
Yes 194 (26.1) No 460 (64.7) Do not know 57 (7.7) Not reported 33 (4.4)
Mean neck circumference □ SD, cm† 39 □ 4.4

* Because 632 (84.4%) of the 744 respondents did not provide information about their ethnicity, this information was excluded from analysis.
† Because 321 (43%) of the 744 respondents did not provide information about neck circumference, this information was excluded from analysis.

dred three (47.9%) respondents reported snoring at least three to four times per week, and 221 (52.1%) said that they did not snore more than one to two times per week. Two hundred seventy-four (54.9%) respondents reported that their snoring bothered other people, whereas 225 (45.1%) denied that it did. In 66 (11.1%) respondents, breathing pauses during sleep were observed by others at least 1 to 2 times per month; in 31 (5.2%) respondents, breathing pauses were observed more than 3 to 4 times per week. Two hundred forty-three (33.8%) respondents stated that they did not feel rested after a night's sleep at least 3 to 4 times per week; 476 (66.2%) felt this way less often or not at all. Two hundred seventy-nine (38.8%) respondents said that they experienced waketime tiredness or fatigue at least 3 to 4 times per week; 441 (61.2%) experienced this problem one to two times per week or less often.

Of 721 (96.9% of the sample) respondents to the question about drowsiness behind the wheel, 137 (19.0%) said that they had nodded off or fallen asleep while driving. Fifteen respondents (4.4%) reported that they nodded off at the wheel at least three to four times per week. Table 2 shows the numbers of patients with these characteristics in each risk group.

Internal Validity

The reliability among individual questions within symptom categories was examined as a measure of internal validity. The Cronbach □ value was 0.92 for correlation of questions within category 1 and 0.63 for category 2. When the question about sleepiness behind the wheel was excluded, the Cronbach □ value in category 2 increased to 0.86.

Roger Stuart
rstuart@wcfgroup.com

Erin, A brief comment on Dr.Fishman's letter:

1. Treating physicians are not against relieving pain for our patients. However, a growing number question the efficacy of opioids for long term relief of chronic pain. Studies indicate modest improvement. Even the article cited by Dr. Webster (Noble J Pain Symptom Management 2008) notes only weak evidence without providing support for "high dose" treatment. That being said, basing opioid guidelines on the expert opinion that touted oxycontin as minimally addicting, and uses an arbitrary ceiling of "toxicity or pain relief" needs to be examined carefully based on the best available evidence.

2. Dr. Fishman says the "heart of the problem is the failure of the guideline to recognize that the supply of specialists is limited." He notes "there must be 15,000 people in the state who are on over 120 milligrams." One might consider the real problem to be the fact that there are 15,000 people in the state of Washington on over 120 milligrams of morphine. Such drug use was based on weak evidence for opioids and absent evidence of better results with "high dose". Perhaps educating the public and physicians about the modest benefit and the associated adverse effects will help reduce the need. The Utah Guides certainly do not consider 120 milligrams "safe" and have gone to great lengths to single out the increased risks associated with methadone. However, it can be stated with certainty that higher doses of opioids carry a higher risk of adverse reactions including death. Their use in cancer vs non cancer patients is historically based on the early studies in terminal cancer. Treatment of long term survivors with opioids and "high dose" opioids carries the same risks as non cancer patients.

3. Dr. Fishman suggests focusing physician education on how to appropriately prescribe and monitor opioids. However, as he notes in his letter, "some evidence shows that specialists and non specialist share a similar rate of unintentional overdose deaths among patients". This strongly supports the need for a fundamental change in the paradigm abandoning the escalation of opioid therapy to toxicity or pain relief. (The goal of full pain relief is rarely if ever achieved). We must abandon the focus on pain leading to polypharmcy of drug on drug as they fail to provide pain relief.

4. Dr. Fishman asks if it the cost of higher doses of brand name opioids is the issue. Speaking for WCF the cost of oxycontin is not cheap. But the real cost has been dysfunction, that is loss of family support, loss of meaning / goals in life, and loss of employability. Free oxycontin would still "cost" too much.

5. Finally, stating the obvious, given appropriate physician and patient education, "high dose" opioid therapy increases problems for the patient and society. For patients, if they are already at or near their maximum dosage, taking "extra", even if it is because they have been conditioned to take extra for "break through pain", are:

- Experiencing drug induced hyperthesia;
- Experiencing drug craving ("addiction"); or
- Experiencing depression (which may or may not be aggravated by opioids); or
- Are simply confused due to drug induced mental impairment.

The consequences are more likely to be catastrophic. Having stronger opioids and more of them further increases the risk. For society, having
the current unrestrained use of opioids for essentially any and all pain has resulted in the current epidemic of prescription addiction. The
current recommendation for having a "ceiling " is not immutable. It may need to be increased or lowered in keeping with future research, but given
the above problems, it is more reasonable than placing patients and society at risk without good evidence of substantial benefit.

I did not put 9.2 in front of 6.1 due to lack of computer skills but agree
that the emphasis is appropriate.

Roger Stuart (Additional Comment/Letter)
rstuart@wcfgroup.com

WCF

August 12, 2008

Ms. Johnson,

I share Dr. Holmes' concerns that the proposed guidelines have not adequately addressed the root cause of our current crisis. Because of this failure, the proposed guidelines do not provide a real platform to achieve lower levels of opiates in the community. This is most disappointing.

Specifically, while not directly supporting the marketing strategy of increasing opiates until relief or intolerable side effects, the guidelines do little to offset the effect of decades of promotion. Promotion that deliberately minimized the problem of "addiction", and resulted in a criminal indictment of the CEO of Purdue Pharmaceuticals.

In my opinion, the real tragedy of this situation is its impact on patients and their families. These are the people who have experienced the severe side effects, including needless deaths, from essentially unrestrained prescriptions of opiates. Prescriptions which have been written without any high quality medical studies to support the practice.

The vast majority of studies for opiate efficacy for chronic pain are for less than a year. To apply these studies to young and otherwise healthy individuals with chronic pain, who can be expected to live for many years simply, defies logic. It has long been known that chronic use of opiates is associated with the development of tolerance. Simply put, it means that the longer the patient is on his opiate, the larger the amount needed to achieve the same benefit. Unfortunately this may be further complicated by paradoxical increased sensitivity to painful stimulus and/or attempts to maintain the euphoria/pain relief first experienced with their introduction to opiates. The latter is especially a risk with some of the newer potent opiates such as OxyContin and Actiq.

It is well documented that the adverse effects of opiate medication increases with the dosage. Untimely, premature death is the one that has garnered the spotlight. But, premature death is only one of a many adverse reactions. Chronic opiate medications have been linked to immune suppression, hormone abnormalities (testosterone depletion is the most widely described), sleep apnea, depression, and "addiction".

To pretend there is a clear indication identifying when desire for the drug outweighs or is comparable to the need for pain control, when it simply does not exist for either the patient or the treating physician, is an illusion. To pretend that "addiction" is not a problem for a significant number of chronic pain patients does not serve the patients or the people of Utah well.

The facts above clearly support caution, restraint, and a balanced approach when prescribing and using opiates. This should not, in my opinion, mean that opiates never be prescribed for chronic pain. But, it should be a wakeup call to change the current prescribing habits in the medical community.

To change prescribing habits, meaningful practice guidelines are needed. Such guidelines should:

#1 Make clear what studies are available to support opiate use in chronic pain. The guideline should list the date, duration, quality rating (as applied to chronic pain long term management vs acute or subacute management of chronic pain) and results of the studies, in an updated table form, as was done in the Oregon guidelines;

#2 Specifically highlight if a listed study supports or refutes the use of high dose opiates for providing any significant benefit, over moderate doses for chronic maintenance;

#3 In the absence of any high quality studies to support the benefit of high level opiates, recommend that in general opiates for chronic non malignant pain be limited to moderate levels. (The New England Journal of Medicine suggested 200 mg of morphine or equivalent could be used if there are not high quality studies to justify either a higher or lower amount);

#4 Highlight whether any of the studies support the benefit of the practice of regular/frequent use of short acting opiates for breakthrough pain. If not, a statement should be made indicating this is not recommended;

#5 Review whether there are any studies to justify "titrating opiate levels". Based on extensive psychological studies, pain contingent escalation of opiates would appear to be operant conditioning and contribute directly to behavior leading to higher levels of opiate use. Absent high quality studies support such a practice, opiate "titration" should not be recommended;

#6 Highlight the modest benefit of opiate use that has been reported in the higher quality studies. The marketing slogan "you don't have to live with your pain" is deceptive. It would provide a more realistic and obtainable goal to say we (as physicians and caregivers) are in partnership with the patient to help them live a better life even though they have pain. This is especially true since very, very few chronic pain patients are fortunate enough to experience complete resolution of their pain. The patient as a passive recipient of the "cure" from "a god like healer" works only for a minority of patients. This poor history of success has, in fact, been the basis for the current shift to acknowledging patient concerns and problems while empowering patients by encouraging patients to develop realistic goals and to take responsibility to achieve the goals. The use of medications and procedures that do not cure should be a supplement judiciously administered to minimize adverse effects and maximize

benefit. This is especially true in chronic pain since the mechanical/neurological origin of the pain is only a part of the complex psycho-social experience.

The pain movement has raised the awareness of pain and the importance of its recognition. They have championed compassionate care. These are laudable goals. Every effort should be made to improve on the gains that have been made. But, the current utilization of opiates in pursuit of a pain free life has brought about an unacceptably high level of adverse effects.

A more balanced approach, recognizing the need for relief from chronic pain (even modest) and mitigating the adverse effects would be achieved with a restrained use of opiates. Taking the focus off pain and emphasizing:

- Functional goals;
- Improved coping: and
- A better quality of life

would likely help diminish patient perception of pain.

Based on the current medical research, the present out of control proliferation of opiate use does not appear to be justified. This calls for significant departure from the current utilization of opiates and for judicious, compassionate prescribing, while supporting chronic pain patients in their efforts to cope with realistic expectations.
I look forward to working with you to enact meaningful guidelines that provide a real platform to achieve lower levels of opiates in the community.

Yours truly,

Dr. Roger Stuart
WCF Medical Director

Jane MacPherson, MD
janemacmd@mac.com

First, I want to say this appears to be an important project to improve the safety of opioid prescribing practices. I think addressing the use of methadone is especially critical as I have seen some pretty dangerous prescriptions written. One problem I see with this guideline is the absence of addressing cancer related pain. I see repeatedly this guideline does refer to 'chronic non malignant pain' and it also refers to hospice care but no where specifically excludes cancer related pain and it's management, so I believe legally, cancer pain would probably fall under the chronic pain management guidelines that this establishes. In my experience, patients with 'chronic' malignancy related pain often reject opioids as a legitimate option to improve their comfort and function as it is. Many of them are already concerned about addiction risks, which stand as a further barrier to good pain management. Now, if they have to sign a contract, suggesting they may become addicted and requesting that they are subjected to periodic drug screens, I think many of my patients will reject opioids as an option to improve their care. I see this creating a giant step backward in the relief of pain and suffering in those struggling with cancer. Also, the guideline suggests anyone requiring more than 100-200mg MED of opioids be referred to a 'pain specialist", but no where is 'pain specialist' defined. I am board certified in hospice and palliative medicine, which includes and understanding of pain management including methadone, beyond that of most MD's but does not involve performing interventional pain procedures and I do not have broad certification in pain management. Frankly, access to 'pain clinics' is very difficult with long waits, so quite impractical for cancer patients; yet about 25% of our patients, would require a 'pain specialist'. I would recommend that 'pain specialists' include those certified in hospice and palliative medicine to relieve the pressure on patients seeking relief of pain and suffering during the cancer treatment. One other problem you should be aware of is the pressure we are under from insurers, including UT Medicaid, to use 'morphine ER or methadone' as first line pain management treatment and document a treatment failure before they will approve Oxycontin or fentanyl. This is also true with some hospice agencies. Another barrier, is the limit placed on the # of opioids dispensed by certain insurers. Medicaid apparently has a tab limit (#180 of any LA opioid) which results in the need for multiple types of long acting opioids be prescribed which isn't logical or particularly safe, in my opinion. Another area of concern is the apparent restriction of home PCA use, which appears to only be acceptable in hospice patients. Sometimes, I Rx home PCA with opioids, like those used in hospice patients to rapidly gain and maintain adequate analgesia. I haven't had any problems with home PCA's , which allow for improved safety related to lock out intervals on the pump. I typically order HH to monitor analgesic use, and response to treatment. Once the patients pain is managed, then I try to change them to an appropriate oral regimen, including methadone, if they are on high doses of PCA opioids. As a final suggestion, I think if methadone is the leading cause of non illicit opioid deaths, that prescribing it be limited to pain specialists or palliative care specialists. Use of this drug requires very careful monitoring and co-ordination of care with all physicians prescribing ANY other medications for the patient due to impacts on metabolism of the drug. So, in summary, while the guidelines are useful, I would request that the following changes be made: 1. Define pain specialist to include palliative care physicians. 2. Specifically exclude cancer related pain and it's management 3. Acknowledge that home opioid PCA use may be appropriate for not only hospice patients but a select group of patients under supervision of a specialist. 4. Limit prescribing of methadone to physicians with advanced training in it's use. This group needs to address insurance pressures that lead to unusual prescribing practices, especially UT Medicaid. Thank you for reviewing my concerns.

Kurt Hegmann, MD, MPH

kurt.hegmann@hsc.utah.edu

Hi Bob,
I am having trouble finding the place on the web to submit comments for the opioid draft.
Attached is the document after spending considerable time on it. Hope it helps.
Kurt

Re: Opioid Treatment Guidelines Draft

Dear Dr. Rolfs:

Congratulations on completing a draft of the treatment guidelines to address this issue of critical importance to the health of Utah's workers that also affects families and other lives. The boxed recommendations and referencing are particularly helpful and the summary is clearly written. Some of the text in the boxed recommendations does not match the summary recommendations and it is suggested those be identical. Below are some additional suggestions for improvements.

A central thrust of this effort would seem to necessitate education of providers regarding the risks of opioids, which have extraordinarily high risks as documented in the introductory section with very high mortality rates in particular. Tobacco is estimated to kill 1200 Utahns per year, versus over 200 from opioids, yet the number of individuals obtaining tobacco products is far higher. That the risks apparently exceed those of cigarettes doubtlessly is not known by providers or the public and the gravity of this situation is not clearly conveyed in the document. Yet, educating that opioids are a critical public health issue that appears to have a relative risk for death greater than tobacco would seem to be a mandatory educational point to be made.

Another central thrust that may be helpful to convey is that there are four critical points dealing with decisions to prescribe opioids that would seem to be required to be addressed for the draft to fulfill the intent. Those four are: 1) decision to initiate for acute pain, 2) decision to renew a prescription in the acute pain setting, 3) decision to initiate for chronic pain, and 4) decision to renew a prescription in the chronic pain setting. The draft handles some of these critical points, but others seem either incompletely or unaddressed. It is suggested that a discussion of these issues would likely be of help in structuring the guideline.

Below are suggestions regarding specific guideline recommendations. The most important issues that seem to need addressing include:

- The summary of **opioids for acute pain** does not note the most important principles. **While the guidelines note that they are primarily for chronic pain, most of those situations start as acute pain. Therefore, that is a critical decision point that should be carefully addressed and adequate attention to use of opioids for acute pain would seem to be rather important.**

Modifications to the bullets are recommended as follows (ACOEM may be used as references for all of these):

1. Most acute pain is better treated with non-opioid medications (e.g., acetaminophen, NSAIDs, exercises, specific stretches, etc.) than with opioids which have much higher adverse effect profiles in acute pain patients. (Comment: without this statement, the draft could be read as inappropriately suggesting that opioids are appropriate first line treatment options and fails to educate providers on this issue. Reference: ACOEM.)
2. Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice after consideration of other non-opioid pain medications and after benefits are projected to outweigh considerable risks. (Comment: benefits should outweigh the considerable risks. Reference: ACOEM.)
3. Evaluation for risk of opioid abuse and dependency should be conducted that includes a history of substance abuse, alcohol abuse, tobacco use, family history of substance abuse, prior opioid abuse/dependency, requesting opioids by name and psychiatric disorders. Those with current histories of substance and alcohol abuse and uncontrolled psychiatric conditions are particularly poor candidates for opioids. Careful consideration of opioid prescriptions among those otherwise at increased risk is warranted. Those patients treated with opioids for acute pain who fail to recover in a usual timeframe or otherwise deviate from the expected clinical course should be very carefully reevaluated. Current and prior historical issues should be reviewed, including comorbid issues that require discontinuation of the opioids. Such issues may include: substance use, prior substance use history, prior opioid dependency, positive drug screening results. (Comment: some guidance on what to do with these treatment failures is necessary. This is the second major decision point that these guidelines should address to prevent some of the problems with opioids. Reference: ACOEM.)
4. When opioid medications are prescribed for treatment of acute pain, the number dispensed should be no more than the number of doses needed to treat the condition to a level of pain where opioids are no longer necessary. (Comment: opioids should be stopped not when the pain is gone, but when the pain has decreased to an intensity that no longer merits use of opioids.)
5. Opioids for acute pain should generally be prescribed nocturnally for pain and sleep management and either not prescribed during the daytime or at a reduced dose to reduce adverse effect profiles and facilitate earlier functional recovery. (Comment: the earlier functional restoration program elements are in place, including immediate walking/aerobic exercise for LBP, ankle sprains, etc, the sooner the pain is relieved and the better the recovery. The guidelines should facilitate transmission of this important knowledge. Reference: ACOEM.)
6. [not recommended to be changed] When opioid medications……for non-medical purposes.

7. Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain. (Comment: rationale for use of long-acting opioids for acute pain is not apparent. As these are guidelines, it is suggested that even the word "generally" should be struck from this bullet. Reference: ACOEM.)
8. The use of opioids should be reevaluated if persistence of pain is beyond the anticipated time period for acute pain treatment. (Comment: the statement in the draft guidelines is not strong enough. Deviation from expected clinical course is a rationale for evaluation of all treatment interventions, including opioids. Reference: ACOEM.)

- **It is suggested that those acute pain patients who are treated with opioids who deviate from the expected clinical course (e.g., delayed recovery) represent the second major decision point that should be carefully addressed by these guidelines to prevent morbidity and mortality from use of opioids**. Consider drafting text to address this key decision point. For example, "Those patients treated with opioids for acute pain who fail to recover in a usual timeframe or otherwise deviate from the expected clinical course should be very carefully reevaluated. The diagnosis and appropriateness of all interventions should be reviewed. Current and prior historical issues should be reviewed, including comorbid issues that require discontinuation of the opioids. Such issues may include: substance use, prior substance use history, prior opioid dependency, positive drug screening results. If there is no functional improvement and there are historical risks of opioid abuse or dependency, opioids should be tapered and discontinued. (Comment: Some guidance on what to do with these treatment failures is necessary. This is the second major decision point that these guidelines should address to prevent the problems with opioids. Reference: ACOEM).

- The summary recommendations for opioid treatment for chronic pain (p. 7) are suggested to be revised.
    1. The second bullet is recommended to be changed to: "Non-opioid treatment should be attempted first (or documented that another provider tried and failed such appropriate treatments)" (Comment: the current recommendation implies that there is no need to implement other non-opioid treatments. This is unacceptable for CNMP, as the basic elements of a functional restoration program are exercise and psychological/behavioral management. Judicious use of medications is appropriate in some circumstances, however implications that there might not be any other treatment required is not appropriate. Reference: ACOEM.)
    2. The third bullet should be modified to "The provider should screen for risk of abuse or addiction before initiating opioid treatment." (Comment: without such screening, the provider is likely to miss what are probably the largest red flags for opioid problems. It is inconceivable to prescribe these drugs with such high documented mortality rates (see your introductory section) without at least asking a few questions. Reference: ACOEM.)

3. The fourth bullet is recommended to be altered to reverse the sequence of the goals…."…includes measureable goals for improvement of function and reduction of pain" which more appropriately notes the treatment goals in the chronic pain setting. (Reference: ACOEM.)
4. A bullet on drug screening should be added. The evidence is too strong to ignore. Suggest "Regular and unscheduled drug screening should be conducted among patients on chronic opioids. Those either found not having the substance or metabolite in their system OR having other substances in their system should have their opioids discontinued." (Comment see ACOEM, Chronic Pain Guidelines, page 156.)
5. Bullet #9 should be modified to "…A second independent opinion or consult…" to emphasize that it is not acceptable to refer to your partner down the hall for such an opinion.
6. Bullet #12 should be changed to "Clinicians should consider consultation for patients with complex pain conditions, patients with serious or potential co-morbidities (including mental illness, prior substance use) or when the provider is not confident of his or her abilities to manage the treatment. Patients with current substance abuse are not candidates for opioid treatment. (Comment: should clearly note that prior substance use is a risk. Should also note that current substance use is a contraindication. See ACOEM.)
7. Bullet #13 should be modified to note the seriousness of a methadone prescription. Consider, "Methadone is a serious medication with very high adverse effects that has very limited utility in the chronic pain setting. It should only be prescribed by physicians who are familiar with its risks and appropriate use and mandatory careful monitoring." (Reference: ACOEM).

- Just as there is no quality evidence of long term safety and efficacy of opioids for chronic non-malignant pain (CNMP). Also, there is no quality evidence that there is undertreatment of CNMP. That should be clearly noted, as that is another one of the many 'beliefs.'

Below are some additional suggestions for improvements.

- The text would read more easily if there was a uniform term throughout. One suggestion is chronic non-malignant pain (CNMP).
- A definition for acute, subacute and chronic is needed, and the plurality if not a majority of studies use 0-1, 1-3 and >3 months respectively.
- The introductory paragraphs make it clear that opioids are far higher risks to the public's health than guns, with an RR between those 2 risks that must exceed 20:1. Such comparisons are recommended to be placed in the text for appropriate context. (I am not an NRA member).
- Aspects of HIPAA do not apply in the workers compensation setting (Page 18). Without that clarification, the document potentially misleads providers on that issue.

Another critical issue that it is suggested should be addressed in these guidelines is the issue of appropriateness of prescriptions by various providers. In short, non-MD/DOs should not be prescribing opioids without close supervision by a licensed MD/DO. With so strongly increased fatality rates from opioids, combined with documented evidence where many prescriptions in Utah are originating, it seems careful oversight by the most highly trained and/or experienced physicians should be mandatory for inclusion in a guideline.

Most of the boxed recommendations should include the ACOEM Guidelines as they are a source for all of those recommendations. This will help because multiple recommendations currently have no references. To assist with some of the page numbers, below are those specific recommendations and page numbers from the 2008 ACOEM Chronic Pain Chapter update.

Acute 1: Numerous locations throughout the ACOEM Practice Guidelines
Acute 2: ACOEM did not specifically include (self-evident)
Acute 3: ACOEM did not specifically include (self-evident)
Acute 4: Chronic pain chapter, pages 274-275. Other locations as well (e.g., LBP chapter)
Acute 5: Multiple locations. LBP chapter. Chronic pain chapter page 275

Chronic 1.1: Chronic pain chapter pages 272-275
Chronic 2.1: (already references ACOEM)
Chronic 2.2: Chronic pain chapter page 7 (last para), page 10
Chronic 3.1: (already references ACOEM)
Chronic 3.2: Chronic pain chapter page 156 (and appendix)
Chronic 3.3: (Agree with this, but ACOEM does not address as it is state-specific)
Chronic 4.1: Chronic pain chapter, pages 272-274
Chronic 4.2: (already references ACOEM)
Chronic 4.3: Chronic pain chapter, pages 3, 158 (and elsewhere in the Guides)
Chronic 5.1: Chronic pain chapter pages 284-285 lists adverse effects to facilitate this. Also elsewhere in the Guides. See also page 275
Chronic 5.2: Chronic pain chapter pages 8-9 (and elsewhere in the Guides)
Chronic 5.3: Already reference ACOEM
Chronic 5.4: Chronic pain chapter pages 272-275 and elsewhere
Chronic 5.5: Indirectly addressed widely, page 273 (ADLs, e.g.) and behavioral sections, etc.
Chronic 6.1: Chronic pain chapter pages 274-5
Chronic 6.2: Chronic pain chapter pages 274-275
Chronic 6.3: Chronic pain chapter pages 272
Chronic 7.1: Chronic pain chapter pages 275
Chronic 7.2: Chronic pain chapter pages 275
Chronic 7.3: ACOEM did not address as this is a state issue (but I agree)
Chronic 8.1: Chronic pain chapter pages 275 (however suggest emphasis on function)
Chronic 8.2: Chronic pain chapter pages 156, 274-277
Chronic 8.2 (second 8.2 bullet): ACOEM did not address as a state issue (I agree)

Chronic 8.3: Chronic pain chapter pages 155, 275-276
Chronic 8.4: Chronic pain chapter pages 275
Chronic 8.5: Self evident
Chronic 9.1: Chronic pain chapter pages 275-276
Chronic 9.2: Chronic pain chapter pages 276
Chronic 10.1: Chronic pain chapter pages 275
Chronic 10.2: Chronic pain chapter pages 155-158, 275-277
Chronic 10.3: Self evident

Chronic section 11 is largely redundant with section 4 (suggest condensing)
Chronic 11.1: Chronic pain chapter pages 272-275, 277
Chronic 11.2: Chronic pain chapter pages 284-285 lists adverse effects to facilitate this. Also elsewhere in the Guides
Chronic 11.3: This bullet should be modified to note that this applies to "non-electronic medical record prescriptions."
Chronic 11.4: Chronic pain chapter pages 274-277
Chronic 11.5: This bullet is speculative for most cases, as the pain generators are highly controversial for most cases of spine-related pain. For straight-forward pain generators, this bullet is logical.
Chronic 11.6: ACOEM did not appear to directly address this point, though it is suggested throughout
Chronic 11.7: Chronic pain chapter pages 274-277
Chronic 12.1: Chronic pain chapter pages 7, 273, 275-276
Chronic 12.2: Chronic pain chapter pages 276-277
Chronic 12.3: Chronic pain chapter pages 277
Chronic 12.4: This is a rather dangerous issue and the seriousness is not conveyed in the discussion. Suggest a substantial re-write to address the gravity of the potential for substance abuse and opioid dependency. Pages 273, 276-277 and psychological section of the guides
Chronic 13.1: See above recommended changes to convey the gravity in the boxed recommendation

"Weaning attempts on at least an annual basis" is a recommended additional bullet. (Reference: ACOEM).

A further note, Chronic recommendation 8.4 is a particularly hazardous slippery slope and as worded, does not convey that danger. The primary danger is gradually escalating doses.

Non-Opioid Pain management Tool:
This tool is a nice, succinct summary. Some suggestions are below.

<u>The referencing is incorrect. The ACOEM Practice Guidelines has recommendations addressing literally every single item in this list regarding LBP, neck pain, neuropathic pain, post-herpetic pain, fibromyalgia. If additional information is desired, please contact</u>

me. As well, the ACOEM guidelines have extensive reference lists (literally over 2,500), including grading of moderate and high quality studies. It may be more efficient to list ACOEM, list other guides (especially Chou's work) and infer the others.

There is no quality evidence that weight loss is efficacious for treatment, although obviously desirable.

There is significantly more quality evidence for use of Heat to treat LBP than cold, and suggest the tool note that.

The time to being a directed exercise program is at the initial visit (see ACOEM). PT may be indicated early, particularly for Clinical Prediction Rule positive LBP patients.

It is not reasonable to have "no CV risk factors" for Cox-2 inhibitors. The main risks appear to be Vioxx, followed by Celebrex. There is evidence suggesting reduced risks for Ibuprofen and Naproxen in some studies and no reductions in risk in others. Suggest better delineation of these issues.

Back school is not indicated in the acute pain phase. It is generally not indicated before the late-subacute phase, because it takes that long to exhaust possible curative treatments.

Tramadol may be reasonable initial treatment for more severe pain. Suggest it is after NSAIDs and muscle relaxants as well as both have evidence of efficacy.

Manipulation is particularly indicated for those testing positive with the Clinical Prediction Rule. This should be noted. Suggest noting not recommended for those with radicular symptoms with neurological deficit.

Suggest breaking out LBP subacute for 1-3 months and then chronic. Rationale is that there are a number of interventions to try and they stretch into the subacute range to try many of them, but those patients are not necessarily the same as those having had LBP for 15 years.

Evidence of efficacy for facet joint injections is very poor. Identification of pain generators is also poor. This document suggests unlimited access is appropriate, when actually the question is whether they should ever by done. ACOEM settled at one injection to see if one can institute longer-term management strategies, such as exercise programs that can be maintained on a long term basis. There also is no substantial intervention even if one was confident that the facet joint was the pain generator. (e.g., rhizotomy does not work well).

There are several other LBP interventions to consider adding (e.g., SNRIs, acupuncture, discectomy).

It is controversial to state that a steroid injection should be first-line for OA even if only in 1 joint. Most would suggest that other interventions (e.g., NSAIDs) should be attempted first prior to an invasive treatment that could potentially induce a septic joint.

Any anti-depressant is likely effective for fibromyalgia (TCA, SNRI, SSRI).

The document would be improved with inclusion of fear avoidant belief training through many of the diagnoses, as that is also something that providers should know about to improve their patient outcomes.

Consideration for inclusion of CRPS may also improve the document and ACOEM has comprehensively reviewed that subject as well.

In part to assure that the "complete evaluation matrix" is correct with respect to the ACOEM Guidelines, I would appreciate a copy of the matrix as per provisions on page 9.

Please do not hesitate to contact me should you have further questions or need of clarification.

Sincerely,

Kurt T. Hegmann, MD, MPH

Landon Beales

* Notes from telephone conversation with Dr. Landon Beales, retired Internist.

- The Guidelines are more suitable for CE or Medical School instruction format, not for the individual physician to review on personal time. In fact, if done during grand rounds or medical school this information would be very interesting and informative.
- These should not be mandated by law, or else many physicians would stop prescribing opioids all together.
- Based on insurance/healthcare organization restrictions, you don't have time to cover all of the assessments recommended in the guidelines with each patient. You may only have 5 minutes, in which case Drs would just choose not to prescribe an opioid.
- This is well-thought, well-written document, but not realistic/practical for a physician to use. It may lead to physician under prescribing because they can't document all of the assessments/recommendations in the guidelines.
- Drug screening before opioid treatment is not reasonable, unless suspected substance abuse, or risk of substance abuse. Most patients would be offended and the Dr/Patient relationship would deteriorate.
- The goals seem to assume that all pain is self-limiting, not chronic.
- Health Department could provide PCPs with easy-to-read informational materials on safe use of the meds that they could give to patients.
- Didn't notice the issue of combining opioids, benzos, sleep meds.
- Rates of methadone rate may be aggravated by use of other OTC medications that affect liver/metabolism. There may be contributing factors beyond simply methadone use that have lead to high death rate with methadone users.
- There is a recommendation that any adjustments in prescriptions should be made during a face-to-face visit, but many chronic pain patients are bed ridden, so Drs can't practically visit them face-to-face.
- Rec. 11.7 – "Seek legal counsel before reporting suspected pharmaceutical diversion." This recommendation isn't practical. How many Drs are going to leave practice to go visit with an attorney to seek counsel?
- There needs to be a more practical way of tracking use of prescription drugs by patients.

Leonard Paulozzi
lbp4@cdc.gov

Bob,

I've attached my comments on the guidelines. I think this work will be a major resource for Utah clinicians. I'm sure Gary Franklin, who shepherds the WA guidelines, will be very interested in

hearing about them at the meeting. You might also want to make sure he has the opportunity to comment on them. Thanks for the chance to look them over.

Utah Clinical Guidelines on Prescribing Opioids

Utah Department of Health

2008

Comment [LP9]: This is a great piece of work that makes a major contribution to the development of physician guidance on this topic. It is both balanced and thorough. I've put specific comments in the following pages.

Disclosure of funding

This article is based on research conducted at the Utah Department of Health with funding from the Utah State Legislature. Additional funds were contributed to the program by the Utah Labor Commission from Utah Workplace Safety Account, and the Worker's Compensation Fund of Utah.

Background and Introduction

Unintentional fatalities due to prescription medications are an increasing problem in United States and Utah. In the year 2000, the Utah Medical Examiner noted an increase in the number of deaths occurring due to an overdose of prescription opioid medications that are typically used for pain management. Epidemiologic studies of data collected by the Office of the Medical Examiner, as well as from emergency department encounters and controlled substances dispensing confirmed the increases and uncovered an alarming problem.

Comment [LP10]: Is this UT or US data?

During the years 1999–2007 deaths attributed to poisoning by prescription pain medications increased by over 500%, from 39 to 261. Deaths of Utah residents from non-illicit drug poisoning (unintentional or intent not determined) have increased from about 50 deaths per year in 1999 to over 300 in 2007. The increase was mostly due to increased numbers of deaths from prescription opioid pain medications, including methadone, oxycodone, hydrocodone, and fentanyl.

Comment [LP11]: Why not also ref your MMWR here?

Prescribing of opioid medications has substantially increased over the past 10-15 years, including greater use for acute and chronic pain. Distribution to Utah of opioids such as hydrocodone, oxycodone, and methadone increased 6-fold from 1997-2002. In addition, national data document an increase in non-medical use of prescription opioids during the past several years (Sundwall & Rolfs, 2005). From 1990 to 2002, the number of people in the U.S. who reported using prescription pain medications non-medically for the first time that year increased from 600,000 to over 2 million people (SAMHSA, 2004).

Comment [LP12]: I assume this ref cites the NSDUH surveys, but it would be better to cite them directly.

In July 2007, recognizing the need for intervention, the Utah State Legislature passed House Bill 137 appropriating funding to the Utah Department of Health (UDOH) to establish a program to reduce deaths and other harm from prescription opiates as well as to develop medical treatment and quality care guidelines for the state of Utah. The Prescription Pain Medication Program is being led by the Utah Department of Health in collaboration with the Utah Attorney General, the Labor Commission, and the Division of Occupational and Professional Licensure (DOPL).

Comment [LP13]: I use "opioids" because the fully synthetic varieties are not derived from opium.

A key goal of this Guidelines is to seek a balance between appropriate treatment of pain and safety in the use of opioids for that purpose. The Model Policy for the Use of Controlled Substances for the Treatment of Pain[2] (Federation of State Medical Boards, 2004), acknowledged that "undertreatment of pain is…a serious public health problem," but also sought to establish the importance of balance in treating pain in the following sentence:

> *"…the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments."*

As of the time these Guidelines were produced, **adequate evidence was not available to determine the benefits of long-term treatment with opioids for persons with chronic pain due to musculoskeletal and other non-cancer causes on patient function and quality of life** (Von Korff & Deyo, 2004). Despite that lack of evidence, the use of these medications for treatment of these conditions has increased substantially in recent years. In the absence of adequate evidence to determine the true benefits and best practices in use of these medications, these Guidelines were developed to assist physicians who choose to use opioids to treat patients with pain to manage that treatment as safely as possible.

Comment [LP14]: Which, FASMB or Utah's?

The principal focus of these Guidelines is on long term treatment of chronic pain, especially chronic, non-cancer pain. While these recommendations may be useful for patients with cancer and other similar causes of pain that require palliative or hospice care, those patients were not the principal target of the guidelines. The diversion of opioid medications to non-medical uses also has contributed to the increased numbers of deaths; therefore several recommendations for use of these medications to treat acute pain have also been included in an attempt to help limit that public health problem.

Comment [LP15]: You could add somewhere here that NCHS has found that 40% of opioids are prescribed in EDs.

[2] The Model Policy for the Use of Controlled Substances for the Treatment of Pain was developed by the Federation of State Medical Boards and endorsed by the Division of Occupational and Professional Licensing on recommendation of the Physicians Licensing Board)

The Department and its advisors recognized that clinicians have many demands on their time and have attempted to make these guidelines as practical and concise as possible. However, long term use of opioid medications to treat chronic pain carries substantial risks and the benefits of this treatment approach have not been adequately established by appropriate studies. The Department agrees with Von Korff and Deyo (2004) that,

> ***"Long-term opioid therapy should only be conducted in practice settings where careful evaluation, regular follow-up and close supervision are ensured".***

Comment [LP16]: This text seems out of place here.

Smmary of Recommendations

Opioid Treatment for Acute Pain

1) Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after consideration of other non-opioid pain medications.
2) When opioid medications are prescribed for treatment of acute pain, the number of doses dispensed should be no more than the number of doses needed based on usual duration of pain for that condition.
3) When opioid medications are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely, not share with others, and to dispose of properly when the pain has resolved to avoid use of the medications for non-medical purposes.
4) Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where adequate monitoring and assessment for adverse effects can be conducted.
5) The use of opioids should be reevaluated if persistence of pain suggests the need to continue opioids beyond the anticipated time period for acute pain treatment.

Comment [LP17]: It would help if you defined "adequate."

Comment [LP18]: Unclear. Do you mean reevaluated as in allow them to continue to as in consider stopping them?

Opioid Treatment for Chronic Pain

1) A comprehensive evaluation should be conducted before initiating opioid treatment.
2) Consideration should be given to alternatives to opioid treatment, including adequate therapeutic trials, before initiating opioid treatment.
3) The provider should consider and screen for risk of abuse or addiction before initiating opioid treatment.
4) A treatment plan should be established that includes measurable goals for reduction of pain and improvement of function[3].
5) The patient should be informed of the risks and benefits and any conditions for continuation of opioid treatment, ideally in a written and signed treatment contract and plan.
6) Opioid treatment for chronic pain should be initiated as a treatment trial, usually using short-acting opioid medications.

Comment [LP19]: Consideration doesn't seem to match with saying you need adequate therapeutic trials. Sounds like you are saying you should use them (and I would agree).

[3] "Function" as used here is defined broadly to include emotional, cognitive, and psychological function.

7) Regular visits with evaluation of progress against goals should be scheduled during the period when the dose of opioids is being adjusted (titration period).
8) Once a stable dose has been established (maintenance period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored.
9) Continuing opioid treatment after the treatment trial should be a deliberate decision that considers the risks and benefits of chronic opioid treatment for that patient. A second opinion or consult may be useful in making that decision
10) An opioid treatment trial should be discontinued if the goals are not met and opioid treatment should be discontinued at any point if adverse effects outweigh benefits or if dangerous or illegal behaviors are demonstrated.
11) Clinicians treating patients with opioids for chronic pain should maintain records documenting the evaluation of the patient, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed.
12) Clinicians should consider consultation for patients with complex pain conditions, patients with serious co-morbidities including mental illness, patients who have a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her abilities to manage the treatment.
13) Methadone should only be prescribed by clinicians who are familiar with its risks and appropriate use.

Methods

Purpose and Target audience

The guidelines provide recommendations for the use of opioids for management of pain that are intended to balance the benefits of use against the risks to the individual and society and to be useful to practitioners. The target audience is all clinicians who prescribe opioids in their practice.

Comment [LP20]: You might put a list here so it is explicit that this includes or doesn't include dentists, midlevels, etc.

Guideline Evidence Review

The steering committee of the Utah Department of Health's Prescription Pain Medication Program developed the key questions, scope, and inclusion criteria used to guide the evidence review process. The process began with a complete literature review for existing guidelines on pain, chronic pain, opioids, pain management, and related topics. Investigators identified and evaluated 40 separate guidelines. Guidelines were identified through electronic databases, reference lists from evaluated guidelines, and recommendations from experts. Electronic databases that were searched include: PubMed, Medline, CINAHL, and the National Guideline Clearinghouse.

Grading of the Evidence and Recommendations

As guidelines were identified they were reviewed for key information. They were evaluated based on the following categories:

- Title

- Year Published: Guidelines were included only if they were published after the year 1999. Articles published before 2000 were merely noted in the grid by their title and date with no additional information.
- Sponsorship and funding
- Medical Perspective
- Target Audience
- The Process: This describes how the guidelines were created. Most guidelines fell into two categories: "evidence-based" and/or "consensus".
- The Rating Scale: This was based on the quality of research that went into the development of the guidelines. Explicit evidence-based guidelines received higher ratings and less explicit, consensus-based guidelines received lower ratings.

medication after they have recovered, they should dispose of their medication immediately to help protect them from being a target for theft as well as protect others from getting into the medications. The Federal Guidelines on Proper Disposal of Prescription Drugs are included in the Tool Section.

Acute 4 Recommendation: Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where adequate monitoring and assessment for adverse effects can be conducted . Methadone is only rarely (almost never?) appropriate for use in acute pain.

Deleted:

Acute 5 Recommendation: The use of opioids should be reevaluated if persistence of pain suggests the need to continue opioids beyond the anticipated time period for acute pain treatment

Comment [LP21]: I would suggest an additional rec that parenteral use of opioids for acute pain should be discouraged.

Before prescribing opioid treatment for chronic pain:

1. Comprehensive initial evaluation/assessment of patient

1.1 Recommendation: A comprehensive initial evaluation should be performed prior to prescribing opioid medication for chronic pain.
Other guidelines with similar recommendations: 1, 2, 4, 6

There are many reasons for using caution when initiating opioid therapy, therefore the recommended complete initial evaluation is very important. A major goal when prescribing opioids should be to achieve greater benefit than harm to patients. Potential for serious harm exists, up to and including death, due either to overdose or to dangerous behaviors that occur while under the influence of these medications. The harm may affect the patient directly. It also may affect others, either through diversion or because of an act performed by the patient on opioids. The most frequent harms are diversion, misuse, abuse, addiction, and overdose and prediction of which patients will be affected by these harms

is difficult. Initiating opioid treatment often results in short term relief, but that relief might not be maintained. Long-term use of opioid medications to treat chronic pain safely requires commitment of adequate resources to regularly monitor and evaluate outcomes and occurrence of adverse consequences.

The goal of the comprehensive evaluation is to determine the nature of the patient's pain, evaluate how the pain is affecting the patients function and quality of life, identify other conditions or circumstances that could affect the choice of treatment or the approach to managing that treatment, assess and evaluate prior approaches to pain management, and serve as a basis for establishing a plan for treatment and evaluation of treatment outcomes.

The evaluation should specifically address these issues.

1) Assess pain and prior treatment of pain.
- Determine the cause of the pain, whether the pain is acute or chronic.
- Assess previous treatment approaches and trials for appropriateness, adequacy, and outcome.

2) Assess presence of social factors, and medical or mental health conditions that might influence treatment especially those that might interfere with appropriate and safe use of opioid therapy [1]:
- Obtain history of substance use, addiction or dependence (if present, refer to Recommendations 11.2 and 11.3) or
- Identify psychiatric conditions that may affect pain or treatment of pain (if present, refer to Recommendation 11.4)
- Identify use of other medications that might interact with medications used to treat the pain such as benzodiazepines.
- Assess social history, including employment, social network, marital history, and any history of legal problems especially illegal use or diversion of controlled substances.
- Assess for presence of medical conditions that might complicate treatment of the pain, including medication allergy, cardiac or respiratory disease, and sleep apnea or risk factors for sleep apnea

3) Assess effects of the pain on person's life and function.
- Assess the severity of pain, functional status of the patient, and the patient's quality of life using a method/instrument that can be used to evaluate treatment effectiveness.

Tools to accompany Recommendation 1:
- Sheehan Disability Tool
- Pain Management Evaluation Tool

Comment [LP22]: They so outnumber other medication in opioid overdoses that they deserve special emphasis.

2. Consider alternative treatment options

2.1 Recommendation: Be sure to consider all options for therapy, including non-pharmaceutical treatment, before or in conjunction with prescribing opioid medication.
Other guidelines with similar recommendations: 1, 2, 3, 4, 5

Opioid medication may not be the appropriate first line of treatment for a significant proportion of patients with chronic pain. Other measures, such as non-opioid analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), antidepressants, anticonvulsants, and non-pharmacologic therapies (e.g., physical therapy), should be tried and the outcomes of those therapies documented first. Opioid therapy should be considered only when other potentially safer and more effective therapies have not proven beneficial.

Comment [LP23]: The WHO pain ladder might be an appropriate ref here.

2.2 Recommendation: Clinicians should refer to disease-specific guidelines for recommendations for treatment of chronic pain related to specific diseases or conditions.

Tools to accompany Recommendation 2:

- Non-opioid Pain Management Tool

3. Screening for risk of addiction or abuse

3.1 Recommendation: Use a screening tool to assess the patient's risk of misuse prior to prescribing an opioid medication long-term for chronic pain.
Other guidelines with similar recommendations: 3

A number of screening tools have been developed for assessing a patient's risk of misuse of medications. Several of these are included in the Tool Section. The screening tool results are intended to assist the clinician in determining whether opioid therapy is appropriate and in determining the level of monitoring appropriate for the patient's level of risk.

3.2 Recommendation: Perform drug screening before initiating long term opioid treatment for chronic pain.

Comment [LP24]: Good. Great.

The drug screening should be either a urine drug screen or another laboratory test that can screen for the presence of illegal drugs, unreported prescribed medication, or unreported alcohol use. It is recommended that this testing be considered for all patients. When screening is limited to situations when there is suspicion of substance misuse, some misuse may be missed. In one study, testing results at first admission to a pain clinic did not correlate with reported medication use for nearly one-fourth of patients. Most of these discrepancies involved finding substances not reported by the patient; a small minority reported taking medications that were not found on testing (Berndt, Maier, & Schutz, 1993).

The clinician may consider performing a screening test for illegal substances (See list of Urine Drug Testing Devices in the Tool Section), in addition to screening for opioids.

A positive drug screen indicates the need for caution, but does not preclude opioid use for treatment of pain. Consideration should be given to referral to substance abuse counseling and/or to a pain management specialist. If opioid medication is subsequently prescribed, the patient should be more carefully monitored and conditions under which opioids are being prescribed should be well documented in the treatment plan (see Recommendations 5, 6, 8, 12).

Immunoassays can be done in the office. These determine if opioids are present but do not identify specific ones, which can subsequently be determined by confirmatory laboratory testing. However, in many cases, going over the results of the initial in-office test carefully with the patient can eliminate the need for confirmation testing. It is extremely important to keep in mind that immunoassays have both false positive and false negative results. Over-the-counter medication, for example, can cause a positive result [5]. The prescriber may want to consider confirmatory testing or consultation with a certified Medical Review Officer if drug test results are unclear [5].

3.3 Recommendation: The prescriber and/or trusted assistant should check Utah's Controlled Substance Database before prescribing opioids for chronic pain.

Most patients who request treatment for pain are legitimately seeking relief of the pain. However, a subset of patients who present seeking treatment for pain are seeking drugs for recreational use, to support an established addiction, or for profit. Information about past patterns of obtaining controlled substances by the patient, such as obtaining medications from multiple providers or obtaining concurrent prescriptions, can alert the provider to the potential for problems.

The State of Utah's Division of Occupational and Professional Licensing (DOPL) maintains the Controlled Substance Database (CSDB) Program, which is a searchable record of all prescriptions that are filled in the state for controlled substances. The Utah Controlled Substance Database Program was legislatively created and put into effect in 1995. It is used to track and collect data on the dispensing of Schedule II-V drugs by all retail, institutional, and outpatient hospital pharmacies, and in-state/out-of-state mail order pharmacies. The data are disseminated to authorized individuals and used to identify potential cases of drug over-utilization, misuse, and over-prescribing of controlled substances throughout the state. This database is accessible to all controlled substance prescribers online at www.csdb.utah.gov. A "Getting Started" presentation is available to orient first-time visitors to the site. Each prescriber may also designate one trusted assistant for accessing this database on his or her behalf.

Deleted: privilege

Tools to accompany Recommendation 3:

- SOAPP-R
- Opioid Risk Tool
- Prescription Drug Use Questionnaire
- List of Recommended Urine Drug Screens

Without careful guidance this may lead the patient to seek excessive dosing of opioids and to disappointment.

Cognitive impairment may occur when patients are taking opioid medication. Therefore, discuss with patients the need to avoid operating motor vehicles or equipment or performing other tasks where impairment would put them or others at risk.

Ensure the patient does not have any absolute contraindications and review risks and benefits related to any relative contraindications with the patient.

Absolute contraindications for opioid prescribing:

- Allergy to an opioid agent (may be addressed by using an alternative agent)
- Co-administration of drug capable of inducing life-limiting drug-drug interaction
- Active diversion of controlled substances (providing the medication to someone for whom it was not intended)

More detail about absolute contraindications is contained in the Tool Section.

Educate patients and family/caregivers about the danger signs of respiratory depression. Everyone in the household should know to summon medical help immediately if a person demonstrates any of the following signs while on opioids:

Signs of respiratory depression:

- Snoring heavily and cannot be awakened
- Having trouble breathing
- Exhibiting extreme drowsiness and slow breathing
- Having slow, shallow breathing with little chest movement
- Having an increased or decreased heartbeat
- Feeling faint, very dizzy, confused or having heart palpitations.

Comment [LP25]: ?? life-threatening?

Comment [LP26]: If family education is this important, shouldn't there be a mention of prescribing naloxone for family use in some cases?

Deleted: has

5.2 Recommendation: The patient and, when applicable, the family or caregiver should both be involved in the educational process.
Other guidelines with similar recommendations: 1

Educational material should be provided in written form and discussed in person with the patient and, when applicable, the family or caregiver [1].

It is crucial to act within the constraints of the Health Insurance Portability and Accountability Act (HIPAA). HIPAA regulates the conditions

under which information may be obtained about the patient from others, such as family members, and under what conditions discussions about the patient with others are allowed.

5.3 Recommendation: The treatment plan, which defines the responsibilities of both patient and clinician, should be documented.
Other guidelines with similar recommendations: 1, 2, 3, 4

Patient responsibilities include properly obtaining, filling, and using prescriptions, and adherence to the treatment plan. They could also include instructions to keep a pain diary, a diary of daily accomplishments, and/or instructions on how and when to give feedback to the prescriber [1].

The prescribing clinician may consider requiring that the treatment plan, be documented in the form of a treatment "contract" or "agreement" that is signed by the patient.

Patients should be encouraged to store opioid medication in a lock box to keep the medication out of the hands of others who should not have access to it.

Deleted: hem

5.4 Recommendation: The treatment plan should contain goals of treatment, guidelines for prescription refills, agreement to submit to urine or serum medication level screening upon request, and reasons for possible discontinuation of drug therapy.
Other guidelines with similar recommendations: 1, 2, 4, 6

The treatment plan (sometimes referred to as treatment "contracts" or "agreements") should contain the items that were developed jointly by patient and clinician, such as follow-up appointments, the pharmacy and clinician to be used, as well as any non-negotiable demands or limitations the clinician wishes to make, such as the prohibition of sharing or trading the medication or getting refills early. Specific grounds for immediate termination of the contract and cessation of prescribing may also be specified, such as forgery or selling of prescriptions or medications [1, 4] or obtaining them from multiple providers as documented by Utah's Controlled Substance Database Program.

Comment [LP27]: If the clinician develops the treatment plan, does it need to say the patient should go to the clinician?

Optional inclusions in the contract:

- Pill counts may be required as a means to gauge proper medication use [1, 4]
- Prohibition on use with alcohol or certain other medications [1]
- Documentation of counseling regarding driving or operating heavy machinery [1, 3]
- Specific frequencies of urine testing

Ideally, the patient should be receiving prescriptions from one prescriber only and filling those prescriptions at one pharmacy only [1, 4, 6].

Although it is not necessary to include specific consequences for specific non-compliant behaviors, it is recommended to document in the

treatment plan that continuing failure by the patient to adhere to the treatment plan will result in escalating consequences, up to and including termination of the clinician-patient relationship (therefore terminating opioid prescribing by that clinician).

A Sample Treatment Plan for Prescribing Opioids is included in the Tool Section.

5.5 Recommendation: Discuss involvement of family members in the patient's care and request that the patient give written permission to talk with family members about the patient's care.

7. Titration phase

7.1 Recommendation: Follow-up face-to-face visits should occur at least every 2-4 weeks during the titration phase.
Other guidelines with similar recommendations: 1

Comment [LP28]: I think this interval is too long for titrating methadone, so perhaps that exception should be noted.

More frequent follow-up visits may be advisable and caution should be used when prescribing opioid medication if the patient has a known addiction problem, suspected drug-behavior problems, or co-existing psychiatric or medical problems. Frequency of visits should also be based on risk stratification (e.g., as determined by a screening tool) and the clinician's judgment (taking into account the volume of the drug being prescribed and how likely it is to be abused) [2].

7.2 Recommendation: When pain and function have not sufficiently improved on a current opioid dose, a trial of a slightly higher dose could be considered.
Other guidelines with similar recommendations: 1, 2

The rate at which the dosing is increased should balance the risk of leaving the patient in a painful state longer than necessary by going too slowly with the risk of causing harm, including fatal overdose, by going too fast. Ideally, only one drug at a time should be titrated in an opioid-naïve patient [1]. Age, health, and severity of pain should be taken into consideration when deciding on increments and rates of titration. Particular caution should be used in titrating dosing of methadone.

Evidence and other guidelines are not in agreement regarding the risks and benefits of high daily doses of opioid measured in morphine equivalents. However, it seems likely that the risk-benefit ratio is less favorable at higher doses. Clinicians should consider consultation with a pain management specialist for patients receiving high dosages, defined as being above 120-200 mg of morphine equivalent dose per day, consultation with a pain management specialist should be considered [5].

Comment [LP29]: A range doesn't work well in a case definition, does it?

Comment [LP30]: If recs are to be broken down this finely, then this seems like it deserves its own rec.

During titration, all patients should be seen frequently until dosing requirements have stabilized. Patients should be instructed to *Use Only as Directed*, that is, not to change doses or frequency of administration without specific instructions from the clinician.

7.3 Recommendation: During the titration phase, until the patient is clinically stable and is judged to be compliant with therapy, it is recommended that the clinician check the CSDB at least quarterly.

For more information about the CSDB, refer to Recommendation 3.3.

Tools to accompany Recommendation 7:

- Dosing Guidelines

8. Maintenance - Periodic monitoring and dose adjustments:

8.1 Recommendation: Assess each of the following four areas of concern at each visit: Analgesia, activity, adverse effects, and aberrant behavior.
Other guidelines with similar recommendations: 2, 4

These assessments can be remembered as the "four A's" (Passik & Weinreb, 2000):

- Analgesia: inquire about level of pain (current, recent, trends, etc.)
- Activity: assess both the patient's function and overall quality of life
- Adverse events: determine whether the patient is having medication side effects
- Aberrant behavior: regularly evaluate for possible drug abuse-related behavior.

A sample checklist for signs of aberrant behavior is included in the Tool Section [2].

8.2 Recommendation: Drug screening should be performed on randomly selected visits and any time aberrant behavior is suspected

Base the average frequency of random drug screening on the assessed degree of risk of aberrant behavior for the individual patient. Pill counts may be useful in some circumstances. In the case of a patient who is already supposed to be taking opioid medication, this test can also help determine whether the medication is being used as directed by the patient or being diverted.

Comment [LP31]: There is no proper diversion.

Deleted: improperly

8.2 Recommendation: During maintenance phase CSDB should be checked at least annually.

After the titration phase is complete and the maintenance phase is underway, the frequency of checks of the CSDB can be based on clinical judgment, but should be no less than annually. High risk patients and patients exhibiting aberrant behavior should be checked more often. For more information about the CSDB, refer to Recommendation 3.3.

Consider evaluating for possible drug abuse-related behavior at each visit. A sample checklist is included in the Tool Section [2].

Consider additional education for patients at follow-up visits [4].

Review the pathophysiologic hypothesis (to see if the diagnosis is still valid) at each visit [4].

8.3 Recommendation: Continuation or modification of therapy should depend on the clinician's evaluation of progress towards stated treatment goals.
Other guidelines with similar recommendations: 4

These include reduction in a patient's pain scores and improved physical and/or psychosocial function.

If treatment goals are not being achieved, including patient compliance with agreed-upon activity level, despite medication adjustments, the clinician should reevaluate the appropriateness of continued treatment with the current medications [5, 6].

Frequent adjustments, after a reasonable time interval of titration, are an indication for a reevaluation of the underlying condition and consideration of the possibility the patient has opioid hyperalgesia or psychological/physical dependence.

Comment [LP32]: Isn't dependence expected as a matter of course with longterm use of opioids? Don't you mean misuse/abuse?

8.4 Recommendation: Adjustments to previously stable maintenance therapy may be considered if the patient develops tolerance, a new pain-producing medical condition arises or an existing one worsens, or if a new adverse effect emerges or becomes more clinically significant.
Other guidelines with similar recommendations: 1

Options for adjustment include reducing medication or rotating opioid medication. If it is documented that the patient is compliant with agreed-upon recommendation such as exercise, working, etc., addition of supplemental short-acting medications for control of break-through pain exacerbation (e.g., as related to an increase in activity, end-of-dose pain, weather-related pain exacerbation, or specific medical conditions) can be considered as well. If patients do not achieve effective pain relief with one opioid, rotation to another frequently produces greater success (Quang-Cantagrel, Wallace, & Magnuson; 2000).

Only if the patient's situation has changed permanently and consideration has been given to increased risk of adverse events, is it reasonable to consider an ongoing increase in maintenance dosing [1].

If rotating among different opioid medications, refer to a standard dosing equivalence table (See the Dosing Guidelines in the Tool Section), taking into account the current drug's half-life.

In general, if the patient's underlying medical condition is chronic and unchanging, it is recommended that the effective dose achieved through titration not be lowered once the patient has reached a plateau of adequate pain relief and functional level [1].

8.5 Recommendation: Dosing changes should generally be made during a clinic visit.

Comment [LP33]: Is this implying not over the phone? If so, I'd say do.

Other guidelines with similar recommendations: 1

If, as with acute pain, the patient's underlying pain-producing chronic medical condition improves, it is expected that the clinician will begin tapering the patient off the opioid medication. See Recommendation 9 for guidelines on discontinuation. Tapering opioid medication with or without the goal of discontinuation may be performed as described in Recommendation 10 or as described in Strategies for Tapering and Weaning in the Tool Section.

Tools to accompany Recommendation 8:

- Checklist for Adverse Effects, Function, and Opioid Dependence
- Signs of Substance Misuse
- Pain Management Evaluation Tool
- Dosing Guidelines
- Strategies for Tapering and Weaning

Other Issues:

11. Documentation and Medical Records

11.1 Recommendation: A written treatment plan should document objectives that will be used to evaluate treatment success.
Other guidelines with similar recommendations: 1, 2, 4, 6

The objectives should address pain relief, improved physical and psychosocial function, including work and exercise compliance, and should indicate if additional diagnostic tests, consultations, or treatments are planned [4]. See Recommendations 4 and 5 respectively for details on establishing treatment goals and formulation of a treatment plan.

11.2 Recommendation: Patient/family/caregiver education should be documented in the medical record.
Other guidelines with similar recommendations: 1

The patient and/or family/caregiver (as appropriate) should review and sign a copy of the opioid medication education materials they receive. See Recommendation 5.2 for more detail about patient/family/caregiver education.

11.3 Recommendation: The written prescription for opioid therapy should be written on tamper-resistant prescription paper (is such available in Utah? Will they know how to get it?) in a manner to help reduce the likelihood of prescription fraud or misuse.
Other guidelines with similar recommendations: 2

The written prescription for opioid therapy should contain the name of the drug, the strength, the number of dosage units, (written numerically

and in text), how the drug is to be taken, the full name, address, and age of the patient, the name, address, and DEA registration number of the practitioner, and the signature of the physician or other authorized practitioner. It shall be dated and signed on the day when issued. Once the maintenance therapy plateau and goals have been obtained, schedule 2 opioid medications may be prescribed for three months in advance. Each prescription for one month should include the date the prescription is written and the date listed on the prescription as to when it is to be filled.

Comment [LP34]: What of schedule III?

To reduce the chance of tampering with the prescription, write legibly, and keep a copy [2]. See the Tamper Resistant Requirements in the Tool Section.

11.4 Recommendation: Assessment of treatment effectiveness should be documented in the medical record.
Other guidelines with similar recommendations: 2, 4

Document the patient's progress toward treatment goals, including functional status, at every visit, rather than merely reporting the patient's subjective report of decreased pain. Ideally, this progress would be evaluated using validated tools [4].

11.5 Recommendation: The clinician should document the progress of the underlying medical condition that is causing the patient's pain.

Both the underlying medical condition responsible for the pain, if known, and other medical conditions that may affect the efficacy or risks of adverse events should be evaluated and documented at every visit.

11.6 Recommendation: Adherence to the treatment plan should be documented in the medical record.
Other guidelines with similar recommendations: 1

Specific components of the treatment plan for which adherence should be assessed include:

- Use of opioid analgesics
- Follow-up referrals, tests, and other therapies

11.7 Recommendation: Document evidence of aberrant behavior.

Clinicians are encouraged to make use of resources provided by the state of Utah that are designed to assist them in managing patients with aberrant behavior (See Checklist for Adverse Effects, Function, and Opioid Dependence and Signs of Substance Misuse in Tool Section). Referral to law enforcement/legal agencies may be appropriate if actions by patients are occurring that could be criminal in nature [1].

Consult with legal counsel prior to contacting law enforcement [1]. Serious non-adherence issues (illegal, criminal, or dangerous behaviors, including altering of prescriptions) may also warrant immediate discontinuation of opioid therapy. See Recommendation 10.

Tools to accompany Recommendation 11:

- Utah's Tamper Resistant Requirements
- Checklist for Adverse Effects, Function, and Opioid Dependence
- Signs of Substance Misuse

12. Consultation and management of complex patients

12.1 Recommendation: To achieve treatment objectives, clinicians may consider referring a patient to a specialist for additional evaluation as clinically indicated.
Other guidelines with similar recommendations: 4

Comment [LP35]: I think it would be better if you combined 12.1-12.3 with a combined, bullet list of indications.

Prescribers may wish to consider referring patients if any of the following conditions or situations is present or if other concerns arise during treatment:

- The patient has a complex pain condition and the clinician wishes verification of diagnosis
- The patient has significant co-morbidities (including psychiatric illness)
- The patient is high-risk for aberrant behavior or addiction

The main goal of a consultation is for the prescribing clinician to receive recommendations for ongoing treatment.

12.2 Recommendation: Patients with a history of addiction or substance use disorder or who have positive drug screens indicative of a problem should be considered for referral to an addiction specialist for evaluation of recurrence risk and for assistance with treatment.
Other guidelines with similar recommendations: 1, 4, 5

Although this is a desirable approach, it is recognized that following this recommendation may not be feasible in parts of Utah where there is a shortage of readily available addiction specialists. The Directory of Resources in the Tool Section includes information on the available resources for patients such as these.

12.3 Recommendation: Pain patients who are addicted to medications/drugs should be referred to a pain management, mental health or a substance use disorder specialist if one is available, for recommendations on the treatment plan and possibly for assistance in management.

The clinician may consider prescribing opioid medication for pain even if the patient has a self-reported or documented pre-existing problem with opiates, as long as monitoring is performed during titration and maintenance phase.

12.4 Recommendation: Patients with coexisting psychiatric disorder should be receiving ongoing mental health support and treatment while

receiving opioid medication for pain control.

Management of patients with a coexisting psychiatric condition may require extra care, monitoring, or documentation [4, 6]. Many psychotherapeutic drugs are CNS depressants and therefore increase the risk of overdose with opioids. Unless the clinician treating the patient is qualified to provide the appropriate care and evaluation of the coexisting psychiatric disorder, consultation should be obtained to assist in formulating the treatment plan and establishing a plan for coordinated care of both the chronic pain and psychiatric conditions.

Tools to accompany Recommendation 12:

- Strategies for Tapering and Weaning
- Directory of Resources

13. Methadone

13.1 Recommendation: Methadone should only be prescribed by clinicians familiar with its risks and use.

Methadone-related death rates have been increasing in Utah and the U.S. In 2006, methadone was implicated in 30% of non-illicit drug-related deaths in Utah. Methadone was the most common drug identified by the Utah Medical Examiner as causing or contributing to accidental deaths, accounting for a disproportionate number of deaths compared to its frequency of use. Methadone was the single drug most often associated with overdose death and had the highest prescription adjusted mortality rate (PAMR) with an average of 150 deaths for every 100,000 prescriptions during 1998-2004. From 1997–2004, population-adjusted methadone prescriptions increased 727%. The rise in the methadone prescription rate was for treatment of pain and not addiction therapy.

Comment [LP36]: What is the source of this information?

The half-life of methadone is long and unpredictable, increasing the risk of inadvertent overdose. The peak respiratory depressant effect of methadone occurs later and lasts longer after treatment initiation or dosage change than does the peak analgesic effect.

Conversion tables that have been established to assist with converting a patient from another opioid medication to methadone are considered by many experts to be unreliable.

Methadone interacts with several other medications that can alter its metabolism, e.g., benzodiazepines, changing the effects of a given dose on pain and on respiratory depression. Potential for interactions should be considered before starting methadone in the presence of other medications and before starting any medication in a patient taking methadone

Comment [LP37]: You could use a ref here to one of the methadone papers that include tabulated lists of interactions.

Methadone can prolong the QT interval and increase the risk of Torsades de Pointe, and sudden cardiac death. Caution should be used in prescribing methadone to any patient at risk for prolonged QT interval, including those with existing cardiac disease or cardiac conduction abnormalities or taking another medication associated with prolonged QT

Proper Disposal of Prescription Drugs

interval (Arizona Center for Education and Research on Therapeutics, 2008).

Methadone has been associated with central sleep apnea and clinicians should consider obtaining a sleep study in patients treated with methadone, especially at higher

Federal Guidelines:

- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.

doses.

- Mixing prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.
- Flush prescription drugs down the toilet *only* if the label or accompanying patient information specifically instructs doing so (see box).
- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper **disposal**. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.

The FDA advises that the following drugs be flushed down the toilet instead of thrown in the trash:
Actiq (fentanyl citrate)
Daytrana Transdermal Patch (methylphenidate)
Duragesic Transdermal System (fentanyl)
OxyContin Tablets (oxycodone)
Avinza Capsules (morphine sulfate)
Baraclude Tablets (entecavir)
Reyataz Capsules (atazanavir sulfate)
Tequin Tablets (gatifloxacin)
Zerit for Oral Solution (stavudine)
Meperidine HCl Tablets
Percocet (Oxycodone and Acetaminophen)
Xyrem (Sodium Oxybate)
Fentora (fentanyl buccal tablet)
Note: Patients should always refer to printed material accompanying their medication for specific instructions.

Comment [LP38]: I know this is an FDA list, but it seems odd to not include general oxycodone ER, MSContin, or generic fentanyl patches. Are they meant to be included? You might check with FDA on this. I'm not sure they still use this list. A ref to FDA would help.

Comment [LP39]: I did not place any comments in this doc after this point.

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Chris Stock, Pharm.D.
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The educational approach to reducing improper prescribing and dispensing of opioid analgesics and encourage appropriate use of these useful medications is laudable. I have serious concerns about some aspects of these guidelines that will, in many Dr's, pharmacists and patients' minds carry the weight of law. 1) General: There is a general tone that may bias doctors against APPROPRIATE AND NECESSARY treatment of pain in people with a history of substance abuse and even current substance "users" i.e. marijuana users. 2) 5) Use of the term "contract" for medication management agreements is a real turn off. "contract" implies there MUST be a consequence if all conditions are not met over time. The recommended "contract" has little emphasis on the prescribers responsiblities and consequences of they are not adhered to. An "agreement" in my opinion is a more customer/patient focussed term. "Contract", in my opinion, biases toward the prescriber and against the patient. I am opposed to this sort of practice anyway - in medical practice patients with other serious, debilitating conditions that are impacted and worsened by the patients own behaviors are not asked to "contract" for their care or forgo that care. That is just plain wrong! Even against the ethics of patient care!. I would strongly encourage you to eliminate "contracts" as a guideline but if they remain, rename them "agreements" and remove statements about "consequences" or at least state the consequences MAY occur if agreed between the provider and patient. 3) Guidelines 3.2 and 8.2 - recommending drug screens - either laboratory-based or office based - will again put tools that are NOT simple in the hands of prescribers who may not have adequate knowledge for appropriate interpretation. They require extensive knowledge about immunoassay technique to understand false positive and negative results, understanding of pharmacokinetics, understanding of chain of custody, and other often unknown and underappreciated aspects of drug testing. The 3 non-CLIA tests recommended in your tools - should only be recommended (and the American BIO product looks most useful since it has non-opiate opioids) unless the State of Utah has confidence in their performance. Again, APPROPRIATE in-office, even in laboratory, immunoassay testing requires knowledge beyond that possessed by the majority of prescribers. Finally, this guideline discusses possible consultation with an MRO. MRO's focus is on confirmatory testing and any questions directed to them about immunoassay invariably, and appropriately, are answered with "there are false positives and negatives with immunoassay, what are the results of the confirmatory GC/MS." If this suggestion for MRO is left in, an additional "tool" listing Utah MROs would be helpful. 4) Page 55 - Russel Portenoy described and listed behaviors that were suspicious of abuse and those that were NOT predictive of abuse. It was adapted and republished in 2002 and 2008 (Zeigler D, Hannah H. in U.S. Pharmacist May 2008 adapted from Portenoy 1990 and Passik 2002). These lists is superior to the list in the tools from the British Pain Society. 5) The COMM and SOAPP-R assessments - like many such "easy" assessments and tools will take significant provider time if appropriately administered and "scored" to be done correctly, and if used as a cursory screen only puts patients and providers at risk for over interpretation/scoring that will again, bias against prescribing opioids when they may be indicated! Thank you for the opportunity to comment on this important guideline!

Craig A. Getty, RN
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1. Force prescribing physicians to explain in detail their rationale each and every time they prescribe narcotics for acute pain relief. Routinely scribbling out a script for Lortab as a first line analgesic is just not acceptable. 2. Force prescribing physicians to document in visit notes each and every time a client makes an unsolicited request/demand for a narcotic to treat an acute pain episode. 3. Force prescribing physicians to thoroughly document in visit notes each and every time they assess and counsel chronic pain clients for narcotics abuse. 4. Require prescribing physicians, including pain specialists, to have NON-TERMINAL-CANCER-RELATED chronic pain clients assessed by at least two other pain specialists (who are NOT associated with the referring physician's practice) and must be in agreement with the referring physician BEFORE treating with Fentanyl/Duragesic. 5. Require prescribing physicians to schedule follow-up visits every three business days for acute pain clients prescribed narcotics AND only prescribe enough narcotics to cover the time period until next appointment. Plus, the client must be examined at those appointments during an active dose of the narcotic. As a nurse with 30 years of experience in health care, I wholeheartedly endorse aggressive pain management for intractable, terminal cases, but abhor the prolific use of narcotics as a first-line choice in the treatment of moderate acute pain, especially without attempting to use non-narcotic options. This reckless activity is supported by not expecting prescribing physicians to thoroughly explain the rationale that led them to prescribing the narcotic. Simply exposing this activity with the illumination provided by professional scrutiny will help to reduce unnecessary narcotic use.

Peter S Lenz, MD
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I am a practicing Emergency Physician at LDS Hospital and Intermountain Medical Center. In general, I support these guidelines. Drug abusing patients frequently come to ER's with pain complaints and request narcotics. Failure of ER physicians to prescribe these drugs often leads to complaints against us, and can occasionally trigger lawsuits when diagnoses are missed. Tramadol is a problematic drug, with addiction potential, and it causes seizures in overdose. The DOPL controlled substance database is a very helpful tool for tracking prescription drug use, but it is very cumbersome and time consuming to use. During a busy shift, it is not possible to check this database as often as I would like due to the time requirement involved. Physicians who prescribe large quantities of narcotics are often not available after hours, or on weekends, and simply refer their patients to the ER during these times. We are often unable to contact them to discuss patients with pain problems. Patients often fail to tell the truth about taking narcotic pain medication. Patients taking large quantities of controlled substances usually drive with unrestricted driver licenses. I propose the following: 1) Physicians should specifically be legally protected from lawsuits or other punitive actions directed against them for failing to provide narcotic prescriptions. 2) Tramadol use should NOT be encouraged by these guidelines. 3) Failure on the part of a patient to place controlled substances on medication lists when seeing a physician should be a crime, and should result in a notification to the DOPL. 4) Use of the DOPL database should be greatly simplified to encourage its use. 5) Driving a motor vehicle within 24 hours of taking any narcotic should be illegal. 6) A threshold should be established at which point a patient must report narcotic use to the Driver License Division of the Utah DMV. I would suggest prescription of more than 500 mg. of hydrocodone (or equivalent) during a one year period. 7) Require all narcotic prescribing physicians to have 24/7 on-call coverage available by

telephone. 8) Pain clinics should be affiliated with hospitals, and have 24/7 on call coverage with practitioners available to evaluate and admit patients with pain crises, etc. 9) Making it easier for physicians to "just say no," to a patient without fear of retaliation of any type will be the single most effective thing we can do to reduce prescription drug abuse. I would be willing to be involved with one of your working groups, if that would be helpful. Thanks, Peter S Lenz, MD Thanks, PeterS Lenz, MD

Gary Franklin
meddir@u.washington.edu
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Bob,

This is an excellent document; the tools are particularly useful. I think we will probably use some of them. I have attached the document with comments in track changes. Our pharmacy manager also went over it in fine detail and thinks it is terrific. We also added some refs to our guideline that we felt did address other recommendations. In addition to these points, I would offer the following:

Some of the language of your guideline reflects language from older guidelines, such as the VA/DOD guideline. Those older guidelines were created at the beginning of the era of heightened use of opioids for chronic, non-cancer pain, prior to the epidemic of deaths and high morbidity.

Tolerance for euphoria may develop before tolerance for respiratory depression. For example, I edited the following statement apparently taken from the VA/DOD guideline:

"In general, if the patient’s underlying medical condition is chronic and unchanging, and if opioid-associated problems have not become apparent (eg, opioid-induced hyperalgesia, substantial tolerance, or significant adverse effects), it is recommended that the effective dose achieved through titration not be lowered once the patient has reached a plateau of adequate pain relief and functional level [1]. "

Some other points you may wish to include:

1. Define acute (up to 6 weeks of the pain episode) and chronic (after >/= 3 months of the pain episode)
2. I don't see anything in here about not using concomitant benzodiazepines or sedative-hypnotics on a regular basis
3. You could put in some refs about non-pharmacological treatments, say, for chronic low back pain (Chou et al, Ann Int Med 2007; 147: 492-504)
4. Severe constipation can be bad enough to be associated with a need for colectomy-I think this adverse effect should be mentioned. In the same vein, the effects on sex hormones, causing infertility and decreased libido, are important adverse effects related to quality of life.

You all have done a great job.

Thanks for allowing us the opportunity to provide comment.

State of Utah
Labor Commission
SHERRIE HAYASHI
Commissioner

JON M. HUNTSMAN, JR.
Governor
GARY R. HERBERT
Lieutenant Governor

December 8, 2008

Dear Dr. David Sundwall and Dr. Robert Rolfs,

We wish to share specific recommendations regarding the "Utah Clinical Guidelines on Prescribing Opioids" report soon to be released by the Utah Department of Health. We feel strongly about these recommendations and, therefore, reserve the right to withdraw any or all of our names as participants in the development of the guidelines should these critical concepts not be adopted into the final, published guidelines.

We do appreciate the work of those who have contributed to the development of the guidelines, particularly Dr. Robert Rolfs and Erin Johnson.

We believe the guidelines contain valuable information and attempt to address many challenges when narcotics are used to treat chronic pain. However, the focus of these guidelines should be to recommend, encourage and support the use of non opioid treatments for acute and chronic pain. We also believe for the guidelines to reach full value to the citizens of the State of Utah, and particularly to the Utah Labor Commission, the following issues must be directly and clearly addressed:

Recommendation 1: **We recommend the guidelines be based on the best available evidence. In the event of incomplete evidence, the guidelines should promote the principle of maximum patient and community safety. To accomplish this, the following adjustments of the proposed guides are recommended.**

Keep the recommended of a limit of 120mg of ms sulfate or its equivalent. While there is not specific evidence that 120mg is the right amount, absent strong evidence that more is better, this limit is in keeping with the principle of maximizing safety.

The article cited by Dr. Webster in support of the current use of opioids for chronic pain (Noble J Pain Symptom Management 2008) was an excellent review of all of the current literature. The article indicated that there was weak evidence for long term use of opioids for chronic pain without providing any evidence for "high dose" treatment. That being said, basing opioid guidelines on expert opinion that touted OxyContin as minimally addicting, and uses an arbitrary ceiling of "excessive side effects or pain relief" has been proven to clearly not be safe.

Dr. Fishman in his letter to the Health Dept. suggests focusing on physician education and on specifically how to appropriately prescribe and monitor opioids. However, as he notes in his letter, "Some evidence shows that specialists and non specialists share a similar rate of unintentional

overdose deaths among patients." A recent DOPL and coroner review in Utah appears to support this observation. This fact strongly argues the need for a fundamental change in the paradigm "that you do not need to live with your pain". As this unobtainable goal has been marketed to the medical community, providers have responded by escalating opioid therapy

Unless appropriate physician education includes restrained use of opioids, including "high dose" opioids, the current unacceptably high problem rate, including death, will persist for the patient and society. For the patients, who are at or near their maximum dose, the consequences of taking "extra" are more likely to be catastrophic, even if it is because they have been conditioned to take extra for "break through pain", or taking extra is in actuality the result of:

- drug induced increased sensitivity for pain;
- drug craving ("addiction");
- depression (which may have been aggravated by opioids) or
- confusion due to drug induced mental impairment.

Having stronger opioids and more of them further increases the risk. For society, having the current unrestrained use of opioids for essentially any and all pain has resulted in the current epidemic of prescription diversion and addiction.

We all want to relieve pain and suffering. But we must work very hard to avoid making the situation worse by rushing to relieve it with medications that do not clearly have lasting benefit, especially if these medications have very serious side effects.

The current recommendation for a "ceiling" is not immutable. It may need to be increased or lowered in keeping with future research. But given the severity of the above problems, establishing a ceiling is far more reasonable than placing patients and society at risk without good evidence of substantial benefit. We recognize that the "ceiling" is a general recommendation and in individual circumstances it may be exceeded. However, in these cases the special circumstances and objective functional gains (as outlined in the guides) should be documented. The failure to have demonstrated objective gains with opioids up to the "ceiling" is a contraindication for further dose escalation.

In response to Dr. Fishman's letter stating the "heart of the problem is the failure of the guideline [Washington State] to recognize that the supply of specialists is limited". He noted that there "must be 15,000 people in the state [of Washington] who are on over 120 mg [of morphine sulfate]". The real problem is not the supply of physicians; it is the scientifically unsupported use of controlled substances. Perhaps educating the public and physicians about the modest benefit of opioids, the associated adverse effects, and alternate approaches to the management of pain and acknowledging the patient's pain will help reduce the current use. It must be kept in mind that Purdue and Cephalon recently paid large civil and criminal fines for their deliberate false marketing of OxyContin and Actiq for use this group of patients.

Within the section suggesting dose limits, it is also important to address the current practice of using short acting opioids for "breakthrough" pain. The regular use of short acting opioids on a daily basis, on top of the long acting opioid, exposes the patient to operant conditioning which will lead

to elevated opioid dosage. It certainly defeats the purpose of long acting opioids to avoid the "peaks and valleys" that supposedly contribute to the development of addiction. Absent good evidence, and none was apparent in our review of the literature, it should be clearly stated that such treatment is not recommended, and has no evidence to support the practice.

Recommendation 2: **We recommend that the background and introduction section contain an updated review of the serious problems that are now seen with narcotics use for chronic pain. Such information is readily available in the literature.**

Inclusion of quotations from a recent article published in the publication, *Pain Physician* would help clarify why this work has undertaken and why stringent guidelines are now needed:

> ***"A Ten-Year Perspective on the Complexities and Complications of the Escalating Use, Abuse, and Nonmedical Use of Opioids"***
>
> *"Therapeutic opioid use and abuse coupled with the nonmedical use of other psychotherapeutic drugs has shown an explosive growth in recent years and has been a topic of great concern and controversy.* ***Americans, constituting only 4.6% of the world's population, have been consuming 80% of the global opioid supply, and 99% of the global hydrocodone supply, as well as two-thirds of the world's illegal drugs*** [emphasis added]. *With the increasing therapeutic use of opioids, the supply and retail sales of opioids are mirrored by increasing abuse in patients receiving opioids, nonmedical use of other psychotherapeutic drugs for prescription controlled drugs, exploding costs, increasing incidence of side effects, and unintentional deaths. However, all these ills of illicit drug use and opioid use, abuse, and non-medical use do not stop with adults. It has been shown that 80% of America's high school students, or11 million teens, and 44% of middle school students, or 5 million teens, have personally witnessed, on the grounds of their schools, illegal drug use, illegal drug dealing, illegal drug possession, and other activities related to drug abuse. The results of the 2006 National Survey on Drug Use and Health showed that 7.0 million or 2.8% of all persons aged 12 or older had used prescription type psychotherapeutic drugs nonmedically in the past month, 16.387 million, or 6.6% of the population, had used in the past year, and 20.3%, or almost 49.8 million, had used prescription psychotherapeutic drugs nonmedically during their lifetime. Sadly, the initiates of psychotherapeutic drugs used for nonmedical purposes were highest for opioids. Therapeutic opioid use has increased substantially, specifically of Schedule II drugs. Apart from lack of effectiveness (except for short-term, acute pain) there are multiple adverse consequences including hormonal and immune system effects, abuse and addiction, tolerance, and hyperalgesia. Patients on long-term opioid use have been shown to increase the overall cost of healthcare, disability, rates of surgery, and late opioid use."*[1]

Recommendation 3: In the section titled "Initiating, Monitoring, and Discontinuing Opioid Treatment" **we recommend that *before* a physician or a "physician extender" starts someone on chronic or long lasting extended release narcotic medication that a request for a second opinion is obtained from an independent peer that is one not associated financially with the**

requesting physician's practice. Often a peer will consider trying other options rather than jumping directly to a "narcotics trial". At this time it is not unusual for the patient to want to be "rescued" from the primary doctor because the patient is receiving no benefit from the pain treatment. Further, when other treatment options are considered and the realities of the problems with lifelong narcotic use are presented to the patient and their family, it is not unusual for them to desire to try other alternatives.

As the guidelines are currently written, it is recommended that first a trial of opiate therapy be given and then if some nebulous pain relief end point is not obtained, that the "trial" be discontinued.

This is extremely problematic in that approximately 30% of working individuals currently report some moderate pain. These guidelines sanction a "narcotic trial" for anyone with "pain" and then allow for escalation of the narcotic based only upon their subjective complaints.

Narcotics are not benign medications. We are not beginning a trial of an anti-inflammatory or muscle relaxer, of which stopping the drug is simplistic. The narcotic medications we are starting these patients on are extremely addictive and life changing as evidenced by the epidemic of narcotic related death and disability plaguing our state. That is why narcotics are so heavily regulated by the state and federal governments.

We believe that much of the problems with narcotics that Utah is experiencing are because of the marketed philosophy that a trial of narcotics is a benign treatment modality. It has been our experience that most patients, who are started on these medicines for chronic pain, develop significant secondary effects of addiction, hyperalgesia and depression requiring more escalation of the narcotics.

Unfortunately, after taking narcotics, many of patients become "hardwired" for these drugs and from that point on are never the same. Their new problem of pain and narcotics has now has become far bigger than their original pathology, often which is minor. Life for them is now permanently changed. They and their families are often now faced with significant physical addictive issues and psychosocial problems. At this time it becomes exceedingly difficult, if not impossible, for anyone to convince the patient that they should stop taking narcotics. This is because the patient will experience significant withdrawal symptoms with a secondary escalation of pain. That is why individuals who are addicted have a very difficult time stopping their narcotic use themselves. The problem of addiction is now validated with new commercials on the radio advertising for detoxification treatments, which state, "I did not need the medication for pain anymore, I just needed them."

Recommendation 4: **We recommend opiate therapy risks be fully disclosed to the patient and family prior to its use. While any level of opiate therapy carries some risk there is no question that higher doses increase the risks, whether it is sleep apnea, endocrine, immune suppression, etc. This should be stated in unequivocal terms in the Guidelines to provide an offset to the "expert" opinion, of low level of "evidence". Indeed new medical literature validates that individuals who have been given chronic opiates actually do better when taken off of them.** [2]

Medical evidence is poor for the usage of narcotics for chronic pain. One of the most common pain conditions seen in primary care is chronic low back pain. In one recent systematic review, 5 to 24 percent of patients who were prescribed long-term opioids had aberrant drug-taking behavior. The review authors noted that, although clinical trials suggest that opioids are effective for the short-term (less than 16 weeks), the effectiveness of long-term opioids (16 weeks or more) for pain relief and improved physical function is less clear.[3]

Less is known about the use of long-term opioids for other common chronic pain conditions. Recommendations are based on expert opinion and uncontrolled studies; however, several adverse effects are known to be associated with prolonged treatment with opioids. One study showed that the unintended consequences include accident proneness, impaired judgment and cognitive function, a decline in occupational and social function, and strained family relationships.[4]

As physicians we ascribe to the Hippocratic Oath to do no harm, it follows that the burden of proof should be on the advocates for "high dose opiates". The absence of evidence based studies to justify "high dose opiates" (given the documented risks) is sufficient to justify restricting the level of prescribed opiates. As a side benefit, this would provide clarification for physicians to limit opiates (when appropriate) without fear of litigation. Currently there is no good evidence that high dose opiates provide long-term improvement of function or the quality of life.

Recommendation 5: **We recommend in the Opioid Treatment for Acute Pain section:**
(1) Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after failure of all other non-opioid pain medications and treatment modalities.
(2) Physicians should be extremely careful in dispensing narcotics to adolescents. Evidence exists that opioid medication could cause them to become more vulnerable to addiction issues. This should be explained to the patient and parent/guardian.

The guidelines for opioid treatment must be for acute pain. Physicians' should be extremely careful when prescribing narcotics to adolescents. A recent study sponsored by the National Institute on Drug Abuse validates that giving narcotics to adolescents can predispose them to lifelong addiction. This is because an adolescent's brain is still developing, and when their reward system is given the euphoric properties of narcotics at this critical period, it makes them more vulnerable to the drug's effects later in adulthood.[5]

Recommendation 6: **We recommend all members of the Committee should again be asked if they, or their clinic, currently, or in the past, received income directly from the pharmaceutical industry that produces narcotic pain medications. As with any reputable medical article the conflicts of interest should be identified and considered before reading specific recommendations and suggestions. Covering up these conflicts is a disservice to the community and the public trust.**

The guidelines clearly state "Each member signed a Conflict of Interest disclosure. No conflicts were reported." We believe there are obvious conflicts of interest on the panel that must be reported. The above statement gives the impression that the committee had no voices with conflicts of interest.

Recommendation 7: **We recommend the DOPL data base should be maintained and reviewed more fully and frequently to prevent diversion and provide better standards of patient care. Tracking of physicians' use of opioids should be initiated in the State of Utah.**

It is evident that a few liberal or unethical physicians can cause massive community damage. We physicians believe that the professional privilege of writing prescriptions of narcotics comes with significant responsibilities. There can be no management of this privilege and responsibility if there is no measurement. The DOPL data base, if reviewed, could have helped to prevent the addiction and death of many Utah citizens, as well as the associated mayhem felt by their families. Police departments have publicly called for pharmacies and insurance companies to be required to report unusual patterns of prescriptions to law enforcement. That way the authorities could target offending prescribers earlier rather than later.

Recommendation 8: **We recommend the contributions of Representative Bradley M. Daw should be acknowledged in the published guidelines.**

Representative Daw has championed the solutions to this iatrogenic epidemic of dysfunction and death. Without his support, the writing of guidelines would have never been undertaken. He should be acknowledged for his significant contributions.

Recommendation 9: **We recommend on page 5 under the "Disclosure of funding" it be clearly stated that funding entities do endorse the published guidelines.**

We would like to know your thoughts. We look forward to your feedback.

Sherrie Hayashi
Utah Labor Commissioner

Larry D. Bunkall
Industrial Accidents Division Director

Alan L. Colledge, MD
Industrial Accidents Medical Director

Ed Holmes, MD
Member of the WC Advisory Council

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Reo Castleton, President of SL Co. Fire Department Local 1696
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Edward Holmes, M.D. of RMCOEG
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Ray Pickup, President of Workers Compensation Fund
Kent Michie, Commissioner of Utah State Insurance Department
Brad Tibbitts, Director of Property & Casualty Division, Utah State Insurance Dept.
Senator Karen Mayne, Utah Senate
Representative Michael T. Morley, Utah House of Representatives
Representative Bradley M. Daw, Utah House of Representatives
Kurt T. Hegmann, MD, Rocky Mountain, Center for Occupational & Environmental Health at the University of Utah
John Barbuto MD

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[1] www.painphysicianjournal.com Pain Physician 2008: Opioids Special Issue: 11:S63-S88
Laxmaiah Manchikanti, MD and Angelie Singh, BS, BA

[2] A longitudinal study of the efficacy of a comprehensive pain rehabilitation program with opioid withdrawal: Comparison of treatment outcomes based on opioid use status at admission Cynthia O. Townsend *, Jennifer L. Kerkvliet, Barbara K. Bruce, Jeffrey D. Rome, W. Michael Hooten, Connie A. Luedtke, John E. Hodgson Mayo Clinic,
Abstract
Use of opioids for chronic non-cancer pain is controversial and the efficacy of comprehensive pain rehabilitation programs (CPRPs) that incorporate opioid withdrawal requires further investigation. We test the hypothesis that patients with chronic pain and longstanding opioid use who undergo opioid withdrawal in the course of rehabilitative treatment will experience significant and sustained improvement in pain and functioning similar to patients who were not taking opioids. A longitudinal design study compared 373 consecutive patients admitted to the Mayo Clinic Pain Rehabilitation Center at admission, discharge and six-month posttreatment by opioid status at admission. Measures of pain severity, depression, psychosocial functioning, health status, and pain catastrophizing were used to assess between- and within-group differences. Treatment involved a 3-week interdisciplinary pain rehabilitation program focused on functional restoration. Over one-half of patients (57.1%) were taking opioids daily at admission. The majority of patients (91%) completed rehabilitation and 70% of patients who completed the program returned questionnaires six months posttreatment. On admission, patients taking low- and high-dose opioids reported significantly greater pain severity ($P = .001$) and depression ($P = .001$) than the non-opioid group. Significant improvement was found on all outcome variables following treatment ($P < .001$) and six-month posttreatment ($P < .001$) regardless of opioid status at admission. There were no differences between the opioid and non-opioid groups upon discharge from the program or at six months following treatment.
Conclusion: Patients with longstanding CPRP on chronic opioid therapy, who choose to participate in interdisciplinary rehabilitation that incorporates opioid withdrawal, can experience significant and sustained improvement in pain severity and functioning.
 Pain 140 (2008) 177–189
International Association for the Study of Pain. Published by Elsevier B.V. doi:10.1016/j.pain.2008.08.005

[3] Martell BA, O'Connor PG, Kerns RD, et al. Systematic review: opioid treatment for chronic back pain: prevalence, efficacy, and association with addiction. Ann Intern Med. 2007;146(2):116-127.

[4] Streltzer J, Johansen L. Prescription drug dependence and evolving beliefs about chronic pain management. Am J Psychiatry. 2006;163(4):594-598.

[5] Abuse Of Painkillers Can Predispose Adolescents To Lifelong Addiction ScienceDaily (Sep. 11, 2008) — No child aspires to a lifetime of addiction. But their brains might. In new research to appear online in the journal Neuropsychopharmacology this week, Rockefeller University researchers reveal that adolescent brains exposed to the painkiller Oxycontin can sustain lifelong and permanent changes in their reward system – changes that increase the drug's euphoric properties and make such adolescents more vulnerable to the drug's effects later in adulthood. The research, led by Mary Jeanne Kreek, head of the Laboratory of the Biology of Addictive Diseases, is the first to directly compare levels of the chemical dopamine in adolescent and adult mice in response to increasing doses of the painkiller. Kreek, first author Yong Zhang, a research associate in the lab, and their colleagues found that adolescent mice self-administered Oxycontin less frequently than adults, suggesting that adolescents were more sensitive to its rewarding effects. These adolescent mice, when re-exposed to a low dose of the drug as adults, also had significantly higher dopamine levels in the brain's reward center

compared to adult mice newly exposed to the drug. "Together, these results suggest that adolescents who abuse prescription pain killers may be tuning their brain to a lifelong battle with opiate addiction if they re-exposed themselves to the drug as adults," says Kreek. "The neurobiological changes seem to sensitize the brain to the drug's powerfully rewarding properties." During adolescence, the brain undergoes marked changes. For example, the brain's reward pathway increases production of dopamine receptors until mid-adolescence and then either production declines or numbers of receptors decline. By abusing Oxycontin during this developmental period, adolescents may inadvertently trick the brain to keep more of those receptors than it really needs. If these receptors stick around and the adolescent is re-exposed to the drug as an adult, the rush of euphoria may be more addictive than the feeling experienced by adults who had never before tried the drug.

In contrast to illicit drug use among adolescents, the problem of nonmedical use of painkillers such as Oxycontin and Vicodin has escalated in recent years, with the onset of abuse occurring most frequently in adolescents and young adults. Recent studies by the National Institute on Drug Abuse and the Substance Abuse and Mental Health Services Administration have shown that 11 percent of persons 12 years old or older have used a prescription opiate illicitly. "Despite the early use of these drugs in young people, little is known about how they differentially affect adolescent brains undergoing developmental change," says Kreek. "These findings gives us a new perspective from which to develop better strategies for prevention and therapy." This research was supported by the National Institute on Drug Abuse.

Gary M Franklin

Summary of Recommendations

Opioid Treatment for Acute Pain

1) Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after consideration of other non-opioid pain medications.
2) When opioid medications are prescribed for treatment of acute pain, the number dispensed should be no more than the number of doses needed based on usual duration of pain for that condition.
3) When opioid medications are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely, not share with others, and to dispose of properly when the pain has resolved to avoid use of the medications for non-medical purposes.
4) Long duration-of-action Schedule II opioids (list these here) should not be used for treatment of acute pain, including post-operative pain, except in situations where adequate monitoring and assessment for adverse effects can be conducted.
5) The use of opioids should be reevaluated if persistence of pain suggests the need to continue opioids beyond the anticipated time period for acute pain treatment.

Opioid Treatment for Chronic Pain

1) A comprehensive evaluation should be conducted before initiating opioid treatment.
2) Consideration should be given to alternatives to opioid treatment, including adequate therapeutic trials, before initiating opioid treatment.
3) The provider should consider and screen for risk of abuse or addiction before initiating opioid treatment.
4) A treatment plan should be established that includes measurable goals for reduction of pain and improvement of function[4].
5) The patient should be informed of the risks and benefits and any conditions for continuation of opioid treatment, ideally in a written and signed treatment contract and plan.
6) Opioid treatment for chronic pain should be initiated as a treatment trial, usually using short-acting opioid medications.
7) Regular visits with evaluation of progress against goals should be scheduled during the period when the dose of opioids is being adjusted (titration period).
8) Once a stable dose has been established (maintenance period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored.
9) Continuing opioid treatment after the treatment trial should be a deliberate decision that considers the risks and benefits of chronic opioid treatment for that patient. A second opinion or consult may be useful in making that decision

[4] "Function" as used here is defined broadly to include physical, emotional, cognitive, and psychological function.

10) An opioid treatment trial should be discontinued if the goals are not met and opioid treatment should be discontinued at any point if adverse effects outweigh benefits or if dangerous or illegal behaviors are demonstrated.
11) Clinicians treating patients with opioids for chronic pain should maintain records documenting the evaluation of the patient, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed. The results of treatment would most accurately be tracked using validated instruments to measure pain and function.
12) Clinicians should consider consultation for patients with complex pain conditions, patients with serious co-morbidities including mental illness, patients who have a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her abilities to manage the treatment. Consideration of consultation would also be important if the treating physician suspects development of significant tolerance, particularly at doses at or above 120-200 mg.
13) Methadone should only be prescribed by clinicians who are familiar with its risks and appropriate use.

Note: Acute pain is typically defined as occurring during the 1st 6 weeks of a pain episode. Chronic pain is typically defined as pain lasting beyond 3 months of a pain episode.

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Methods

Purpose and Target audience

The guidelines provide recommendations for the use of opioids for management of pain that are intended to balance the benefits of use against the risks to the individual and society and to be useful to practitioners. The target audience is all clinicians who prescribe opioids in their practice.

Guideline Evidence Review

The steering committee of the Utah Department of Health's Prescription Pain Medication Program developed the key questions, scope, and inclusion criteria used to guide the evidence review process. The process began with a complete literature review for existing guidelines on pain, chronic pain, opioids, pain management, and related topics. Investigators identified and evaluated 40 separate guidelines. Guidelines were identified through electronic databases, reference lists from evaluated guidelines, and recommendations from experts. Electronic databases that were searched include: PubMed, Medline, CINAHL, and the National Guideline Clearinghouse.

Grading of the Evidence and Recommendations

As guidelines were identified they were reviewed for key information. They were evaluated based on the following categories:

- Title

- Year Published: Guidelines were included only if they were published after the year 1999. Articles published before 2000 were merely noted in the grid by their title and date with no additional information.
- Sponsorship and funding
- Medical Perspective
- Target Audience
- The Process: This describes how the guidelines were created. Most guidelines fell into two categories: “evidence-based” and/or “consensus”.
- The Rating Scale: This was based on the quality of research that went into the development of the guidelines. Explicit evidence-based guidelines received higher ratings and less explicit, consensus-based guidelines received lower ratings.

For the complete evaluation matrix of the 40 guidelines contact the corresponding author.

In total, 40 guidelines for pain management were reviewed and evaluated. As each guideline was reviewed, it received a rating from 1-10 (for a breakdown of the rating scale, see Appendix A). Guidelines that received scores of seven (7) or lower were excluded. Four (4) sets of guidelines received scores of eight (8) or above. Three public health professionals reviewed the ratings given to ensure that the scores given were consistent with the rating scale.

Panel composition

The Utah Department of Health convened two multidisciplinary panels (see Appendix 1 for complete list of panel members). The Guideline Recommendation Panel convened on four (4) occasions between May and July 2008. Their purpose was to review the evidence and formulate recommendations based on the evidence in the selected guidelines. Each member signed a Conflict of Interest disclosure. No conflicts were reported. The Guideline Implementation and Tool Panel convened twice (2) between July and August 2008 to review the recommendations to ensure that they were implementable as well as to identify tools needed in order to put the recommendations into use. The first panel consisted of twelve (12) experts and the second consisted of nine (9) experts from throughout the state of Utah.

Recommendation Development Process

The guideline recommendation panel met in person on four occasions between May and July 2008. The purpose of the first meeting was to provide panel members with copies of the selected, high-scoring guidelines and to present the purpose and plan for developing the guidelines. Prior to the second meeting, panel members were asked to review the four guidelines for commonalities. The recommendations that were supported by multiple guidelines created the basis of the first draft of the recommendations used by the Guideline Recommendation Panel. Consideration was given to adopting one of the existing evidence-based guidelines outright, but the panel felt that no single guideline represented sufficiently what was desired of the Utah guidelines. The panel voted to include two (2) additional sets of guidelines that had not met the inclusion criteria for consideration while drafting the recommendations. In total, content for the Utah

guidelines was drawn from six (6) guidelines. The key topics to be developed into specific recommendations were posted on a website where the guideline recommendation panelists posted comments and edited the text. The panelists' postings were the basis on which content was selected from the chosen guidelines. This content was then used to create a draft of actual recommendation statements and supporting paragraphs. At the third meeting, a straw poll was taken on the recommendation draft. Through discussion and rewording, consensus on content was achieved for all of the recommendations discussed over the course of the two meetings. Outside the meetings, non-content editing of the recommendations and supporting statements was performed, based on the panel's discussions, to create the final draft of the recommendations and supporting paragraphs.

Tool Development Process

The Guideline Implementation and Tools Panel met in person on two occasions between July and August 2008. Prior to the first meeting, a book was compiled that included all tools that were identified in the forty (40) guidelines. Sample tools were solicited from panel members as well. In total, the workbook contained forty-seven (47) tools. At the first meeting, the panel reviewed the draft recommendations and discussed whether any specific recommendations were impossible or burdensome to implement. Panel members were each given a book containing all the tools. In between the first and second meeting, panel members reviewed and graded each tool according to usefulness and whether or not it should be included in the guidelines. Votes and rating were tallied prior to the second meeting. Tools that received an average rating of below two (2) were eliminated. At the second meeting, the remaining tools were discussed and it was determined which of the remaining tools should be included, modified, or eliminated.

Following the final panel meetings, Utah Department of Health staff formally drafted the complete guidelines document.

Drafts of the complete guidelines were then distributed to all panel members and several Utah Department of Health internal staff for feedback and revisions. External peer reviewers were solicited for additional comments. Prior to publication, the guideline was submitted to the Utah Department of Health Executive Director for approval.

Recommendations

Previously published evidence-based or consensus-based guidelines have been used as the foundation for many of the Utah recommendations. Each guideline has been assigned a number. After each recommendation, the numbers of the guidelines with similar or supporting recommendations are listed.

Reference Guidelines:

1. Department of Veterans Affairs, Department of Defense. (2003). *VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain*
2. College of Physicians and Surgeons of Ontario. (2008). *Evidence-based recommendations for medical management of chronic non-malignant pain*
3. American College of Occupational and Environmental Medicine's Occupation Medicine Practice Guidelines. (2008).
4. *Opioids in the Management of Chronic Non-Cancer Pain: An Update of American Society of the Interventional Pain Physicians' (ASIPP) Guidelines*
5. Washington State Agency Medical Directors' Group. *Interagency guideline on opioid dosing for chronic non-cancer pain: An educational pilot to improve care and safety with opioid treatment*
6. Federation of State Medical Boards of the United States, Inc. *Model policy for the use of controlled substances for the treatment of pain.*

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Opioid treatment recommendations for acute pain:

Acute 1 Recommendation: Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after consideration of other non-opioid pain medications

Acute 2 Recommendation: When opioid medications are prescribed for treatment of acute pain, the number dispensed should be no more than the number of doses needed based on usual duration of pain for that condition

Acute 3 Recommendation: When opioid medications are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely, not share with others, and to dispose of properly when the pain has resolved to avoid use of the medications for non-medical purposes.

It is important for patients to recognize the need to store medications securely. Encourage patients to keep medications in a locked environment rather than in the typical locations of the bathroom or kitchen cabinet where they are accessible to unsuspecting children, curious teenagers, and can be a target for theft. Tell the patient that if they have leftover medication after they have recovered, they should dispose of their medication immediately to help protect them from being a target for theft as well as protect others from getting into the medications. The Federal Guidelines on Proper Disposal of Prescription Drugs are included in the Tool Section.

Acute 4 Recommendation: Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where adequate monitoring and assessment for adverse effects can be conducted

Acute 5 Recommendation: The use of opioids should be reevaluated if persistence of pain suggests the need to continue opioids beyond the anticipated time period for acute pain treatment

Before prescribing opioid treatment for chronic pain:

1. Comprehensive initial evaluation/assessment of patient

1.1 Recommendation: A comprehensive initial evaluation should be performed prior to prescribing opioid medication for chronic pain.
Other guidelines with similar recommendations: 1, 2, 4, 5, 6

There are many reasons for using caution when initiating opioid therapy, therefore the recommended complete initial evaluation is very important. A major goal when prescribing opioids should be to achieve greater benefit than harm to patients. Potential for serious harm exists, up to and including death, due either to overdose or to dangerous behaviors that occur while under the influence of these medications. The harm may affect the patient directly. It also may affect others, either through diversion or because of an act performed by the patient on opioids. The most frequent harms are diversion, misuse, abuse, addiction, and overdose and prediction of which patients will be affected by these harms is difficult. Initiating opioid treatment often results in short term relief, but that relief might not be maintained. Long-term use of opioid medications to treat chronic pain safely requires commitment of adequate resources to regularly monitor and evaluate outcomes and occurrence of adverse consequences.

The goal of the comprehensive evaluation is to determine the nature of the patient's pain, evaluate how the pain is affecting the patients function and quality of life, identify other conditions or circumstances that could affect the choice of treatment or the approach to managing that treatment, assess and evaluate prior approaches to pain management, and serve as a basis for establishing a plan for treatment and evaluation of treatment outcomes.

The evaluation should specifically address these issues.

1) Assess pain and prior treatment of pain.
- Determine the cause of the pain, whether the pain is acute or chronic.
- Assess previous treatment approaches and trials for appropriateness, adequacy, and outcome.

2) Assess presence of social factors, and medical or mental health conditions that might influence treatment, especially those that might interfere with appropriate and safe use of opioid therapy [1]:
- Obtain history of substance use, addiction or dependence (if present, refer to Recommendations 11.2 and 11.3).
- Identify psychiatric conditions that may affect pain or treatment of pain (if present, refer to Recommendation 11.4).
- Identify use of other medications that might interact with medications used to treat the pain.
- Assess social history, including employment, social network, marital history, and any history of legal problems especially illegal use or diversion of controlled substances.
- Assess for presence of medical conditions that might complicate treatment of the pain, including medication allergy, cardiac or respiratory disease, and sleep apnea or risk factors for sleep apnea

3) Assess effects of the pain on person's life and function.
- Assess the severity of pain, functional status of the patient, and the patient's quality of life using a method/instrument that can be used to evaluate treatment effectiveness.

Tools to accompany Recommendation 1:
- Sheehan Disability Tool

Deleted: or

- Pain Management Evaluation Tool

2. Consider alternative treatment options

2.1 Recommendation: Be sure to consider all options for therapy, including non-pharmaceutical treatment, before or in conjunction with prescribing opioid medication.
Other guidelines with similar recommendations: 1, 2, 3, 4, 5

Opioid medication may not be the appropriate first line of treatment for a significant proportion of patients with chronic pain. Other measures, such as non-opioid analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), antidepressants, anticonvulsants, and non-pharmacologic therapies (e.g., physical therapy), should be tried and the outcomes of those therapies documented first. Opioid therapy should be considered only when other potentially safer and more effective therapies have not proven beneficial.

2.2 Recommendation: Clinicians should refer to disease-specific guidelines for recommendations for treatment of chronic pain related to specific diseases or conditions.

Tools to accompany Recommendation 2:

- Non-opioid Pain Management Tool

3. Screening for risk of addiction or abuse

3.1 Recommendation: Use a screening tool to assess the patient's risk of misuse prior to prescribing an opioid medication long-term for chronic pain.
Other guidelines with similar recommendations: 3

A number of screening tools have been developed for assessing a patient's risk of misuse of medications. Several of these are included in the Tool Section. The screening tool results are intended to assist the clinician in determining whether opioid therapy is appropriate and in determining the level of monitoring appropriate for the patient's level of risk.

3.2 Recommendation: Perform drug screening before initiating long term opioid treatment for chronic pain.

The drug screening should be either a urine drug screen or another laboratory test that can screen for the presence of illegal drugs, unreported prescribed medication, or unreported alcohol use. It is recommended that this testing be considered for all patients. When screening is limited to situations when there is suspicion of substance misuse, some misuse may be missed. In one study, testing results at first admission to a pain clinic did not correlate with reported medication use for nearly one-fourth of patients. Most of these discrepancies involved finding substances not reported by the patient; a small minority reported taking medications that were not found on testing (Berndt, Maier, & Schutz, 1993).

The clinician may consider performing a screening test for illegal substances (See list of Urine Drug Testing Devices in the Tool Section), in addition to screening for opioids.

A positive drug screen indicates the need for caution, but does not preclude opioid use for treatment of pain. Consideration should be given to referral to substance abuse counseling and/or to a pain management specialist. If opioid medication is subsequently prescribed, the patient should be more carefully monitored and conditions under which opioids are being prescribed should be well documented in the treatment plan (see Recommendations 5, 6, 8, 12).

Immunoassays can be done in the office. These determine if opioids are present but do not identify specific ones, which can subsequently be determined by confirmatory laboratory testing. However, in many cases, going over the results of the initial in-office test carefully with the patient can eliminate the need for confirmation testing. It is extremely important to keep in mind that immunoassays have both false positive and false negative results. Over-

the-counter medication, for example, can cause a positive result [5]. The prescriber may want to consider confirmatory testing or consultation with a certified Medical Review Officer if drug test results are unclear [5].

3.3 Recommendation: The prescriber and/or trusted assistant should check Utah's Controlled Substance Database before prescribing opioids for chronic pain.

Most patients who request treatment for pain are legitimately seeking relief of the pain. However, a subset of patients who present seeking treatment for pain are seeking drugs for recreational use, to support an established addiction, or for profit. Information about past patterns of obtaining controlled substances by the patient, such as obtaining medications from multiple providers or obtaining concurrent prescriptions, can alert the provider to the potential for problems.

The State of Utah's Division of Occupational and Professional Licensing (DOPL) maintains the Controlled Substance Database (CSDB) Program, which is a searchable record of all prescriptions that are filled in the state for controlled substances. The Utah Controlled Substance Database Program was legislatively created and put into effect in 1995. It is used to track and collect data on the dispensing of Schedule II-V drugs by all retail, institutional, and outpatient hospital pharmacies, and in-state/out-of-state mail order pharmacies. The data are disseminated to authorized individuals and used to identify potential cases of drug over-utilization, misuse, and over-prescribing of controlled substances throughout the state. This database is accessible to all controlled substance prescribers online at www.csdb.utah.gov. A "Getting Started" presentation is available to orient first-time visitors to the site. Each prescriber may also designate one trusted assistant privilege for accessing this database on his or her behalf.

Tools to accompany Recommendation 3:

- SOAPP-R
- Opioid Risk Tool
- Prescription Drug Use Questionnaire
- List of Recommended Urine Drug Screens

Establishing Treatment Goals and a Written Treatment Plan:

4. Establish treatment goals

4.1 Recommendation: The use of opioids should be part of a written treatment plan that is tailored to the patient's circumstances and the characteristics of the pain.

The prescribing of opioids to treat chronic pain should take into account the pathophysiology of the pain. Knowing the pathophysiology helps to predict whether opioid medication is likely to help reduce pain or to improve function and therefore should be considered when establishing treatment goals. Non-opioid treatment modalities should be included in the treatment plan whenever possible, to maximize the likelihood of achieving treatment goals.

4.2 Recommendation: Goals for treatment of chronic pain should be measurable and should include improved function and quality of life as well as improved control of pain.
Other guidelines with similar recommendations: 1, 3, 5

For most chronic pain conditions, elimination of pain is an unreasonable goal [2]. Goals for treatment of chronic pain should include improvement in the tolerability of the pain and in function [2]. The clinician should counsel the patient on reasonable expectations for treatment outcomes so that together they can agree on achievable treatment goals addressing both pain and function. In the small subset of cases where functional improvement is not likely to occur, improved quality of life may be the main treatment goal.

The pathophysiologic basis of the pain should be considered in order to establish a prognosis for future improvement (or worsening) in function and pain, and therefore should influence the goals of treatment.

Goals for functional improvement and measures to track progress against those goals should be established and documented to serve as a basis of evaluating treatment outcome [1, 3]. These include:

- Objective physical findings obtained by the examining clinician (e.g., improved strength, range of motion, aerobic capacity, and frequency and intensity of conditioning)
- Functional status at work (e.g., increase in physical output, endurance, or ability to perform job functions)
- Functional status at home (e.g., increased ability to perform instrumental activities of daily living)

Targets for improved quality of life should also be identified and documented to serve as a basis for evaluating treatment outcomes. These may include:

- Patient rating of quality of life on a measurement scale
- Psychosocial status (e.g., increased social engagement or decreased emotional distress)
- Familial status (e.g., improved relationships with or decreased burden on family members)
- Physical status (e.g., increased ability to exercise, perform chores, or participate in hobbies).

Pain intensity should be assessed at each visit using a standard instrument such as the Numerical Rating Scale (See the Pain Management Evaluation Tool, Patient Pain and Medication Tracking Chart, Sheehan Disability Scale, and Brief Pain Inventory Form in the Tool Section and page 17 of VA/DOD guidelines).

Clinicians should consider cultural differences in assessing function, quality of life, and pain intensity (See http://prc.coh.org/culture.asp for examples). These measures of improvement could be reported by the patient, family members, and/or the employer. Permission to discuss the patient's condition with these persons should have previously been obtained and documented (See Recommendation 5.5).

4.3 Recommendation: Treatment goals should be developed jointly by patient and clinician
Other guidelines with similar recommendations: 2, 5

Engage patients in their own healthcare. Clinicians have observed that when patients assume a significant portion of the responsibility for their rehabilitation they are more likely to improve and that when they participate in goal setting they are more likely to achieve the goals. As with any other chronic illness (such as diabetes or heart disease), the clinician should focus not just on pain control, but also on treating patients' underlying diseases and encouraging them to engage in ownership of their own health.

Tools to accompany Recommendation 4:

- Pain Management Evaluation Tool
- Patient Pain and Medication Tracking Chart
- Sheehan Disability Scale
- Brief Pain Inventory Form
- Sample Treatment Plan for Prescription Opioids
- Cultural considerations in assessing function, quality of life, and pain intensity: http://prc.coh.org/culture.asp

5. Informed consent and formulation of a treatment plan

5.1 Recommendation: Counsel the patient on the risks and benefits of opioid therapy before initiating that treatment..

Other guidelines with similar recommendations: 4

The patient should be counseled about the risks of developing tolerance, physical or psychological dependence, and withdrawal symptoms, as well as about appropriate use of the medication and possible adverse effects [4, 5]. Adverse effects can include hypogonadism with secondary osteoporosis [3], opioid-induced hyperalgesia [3, 5], allodynia [5], abnormal pain sensitivity [5], and depression (Daniell, 2007).

Patients should be informed not to expect complete relief from pain. The excitement and euphoria of initial pain relief that may occur with a potent opioid can lead the patient to expect long term complete pain relief. Without careful guidance this may lead the patient to seek excessive dosing of opioids and to disappointment.

Cognitive impairment may occur when patients are taking opioid medication. Therefore, discuss with patients the need to avoid operating motor vehicles or equipment or performing other tasks where impairment would put them or others at risk.

Ensure the patient does not have any absolute contraindications and review risks and benefits related to any relative contraindications with the patient.

Absolute contraindications for opioid prescribing:

- Allergy to an opioid agent (may be addressed by using an alternative agent)
- Co-administration of drug capable of inducing life-limiting drug-drug interaction
- Active diversion of controlled substances (providing the medication to someone for whom it was not intended)

More detail about absolute contraindications is contained in the Tool Section.

Educate patients and family/caregivers about the danger signs of respiratory depression. Everyone in the household should know to summon medical help immediately if a person demonstrates any of the following signs while on opioids:

Signs of respiratory depression:

Periods of ataxic (irregular) breathing or other sleep disordered breathing

- Snoring heavily and cannot be awakened
- Having trouble breathing
- Exhibiting extreme drowsiness and slow breathing
- Having slow, shallow breathing with little chest movement
- Having an increased or decreased heartbeat
- Feeling faint, very dizzy, confused or has heart palpitations.

5.2 Recommendation: The patient and, when applicable, the family or caregiver should both be involved in the educational process.
Other guidelines with similar recommendations: 1

Educational material should be provided in written form and discussed in person with the patient and, when applicable, the family or caregiver [1].

It is crucial to act within the constraints of the Health Insurance Portability and Accountability Act (HIPAA). HIPAA regulates the conditions under which information may be obtained about the patient from others, such as family members, and under what conditions discussions about the patient with others are allowed.

5.3 Recommendation: The treatment plan, which defines the responsibilities of both patient and clinician, should be documented.
Other guidelines with similar recommendations: 1, 2, 3, 4, 5

Patient responsibilities include properly obtaining, filling, and using prescriptions, and adherence to the treatment plan. They could also include instructions to keep a pain diary, a diary of daily accomplishments (eg, an activity log), and/or instructions on how and when to give feedback to the prescriber [1].

The prescribing clinician may consider requiring that the treatment plan, be documented in the form of a treatment “contract” or “agreement” that is signed by the patient.

Patients should be encouraged to store opioid medication in a lock box to keep the medication out of the hands of others who should not have access to them.

5.4 Recommendation: The treatment plan should contain goals of treatment, guidelines for prescription refills, agreement to submit to urine or serum medication level screening upon request, and reasons for possible discontinuation of drug therapy.
Other guidelines with similar recommendations: 1, 2, 4, 5, 6

The treatment plan (sometimes referred to as treatment "contracts" or "agreements") should contain the items that were developed jointly by patient and clinician, such as follow-up appointments, the pharmacy and clinician to be used, as well as any non-negotiable demands or limitations the clinician wishes to make, such as the prohibition of sharing or trading the medication or getting refills early. Specific grounds for immediate termination of the contract and cessation of prescribing may also be specified, such as forgery or selling of prescriptions or medications [1, 4] or obtaining them from multiple providers as documented by Utah's Controlled Substance Database Program.

Optional inclusions in the contract:

- Pill counts may be required as a means to gauge proper medication use [1, 4]
- Prohibition on use with alcohol or certain other medications [1]
- Documentation of counseling regarding driving or operating heavy machinery [1, 3]
- Specific frequencies of urine testing

Ideally, the patient should be receiving prescriptions from one prescriber only and filling those prescriptions at one pharmacy only [1, 4, 5, 6].

Although it is not necessary to include specific consequences for specific non-compliant behaviors, it is recommended to document in the treatment plan that continuing failure by the patient to adhere to the treatment plan will result in escalating consequences, up to and including termination of the clinician-patient relationship (therefore terminating opioid prescribing by that clinician).

A Sample Treatment Plan for Prescribing Opioids is included in the Tool Section.

5.5 Recommendation: Discuss involvement of family members in the patient's care and request that the patient give written permission to talk with family members about the patient's care.

This is best done before starting to treat the patient because it can be more difficult to obtain consent after an issue occurs. Prior to initiating treatment with opioids, the physician my want to consider a family conference to help assess the patient's integrity [4]. Consultation with others, however, must only be done within the constraints of HIPAA, as noted above (See Recommendation 5.2).

Tools to accompany Recommendation 5:

- Absolute Contraindications to Opioid Prescribing
- Sample Treatment Plan for Prescribing Opioids

Initiating, Monitoring, and Discontinuing Opioid Treatment:

6. Initiate trial of opioid therapy

6.1 Recommendation: Opioid medication should be initiated as a short-term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life.

The clinician should clearly explain to the patient that initiation of opioid treatment is not a commitment to long-term opioid treatment and that treatment will be stopped if the trial is determined to be unsuccessful. The trial should be for a specific time period with pre-determined evaluation points. The decision to continue opioid medication treatment beyond

the trial period should be based on the balance between benefits, including function and quality of life, and adverse effects experienced. Criteria for cessation should be considered before treatment begins. Refer to Recommendation 9 for more information on discontinuation of treatment.

6.2 Recommendation: In most instances, the trial should begin with short-acting opioid medication.

Short-acting opioid medications are in general safer and easier to titrate to an effective dose. If the treatment trial proves successful in achieving the goals established in the treatment plan, the prescriber may consider switching the patient to a long-acting or sustained-release formulation (See the Dosing Guidelines in the Tool Section). The patient's individual situation should influence whether the patient is switched from short-acting medication.

Treatment with long-acting opioid medication before a trial using a short-acting medication has been performed is an option that should be prescribed only by those with considerable expertise in chronic pain management.

6.3 Recommendation: Parenteral (intravenous, intramuscular, subcutaneous) administration of opioids for chronic pain is, in general, discouraged.*
Other guidelines with similar recommendations: 2

Daily IM or SC injections should be avoided except under a highly supervised environment such as during an admission to the hospital or hospice.

*These guidelines did not consider intrathecal administration and this recommendation was not intended to discourage trained and qualified physicians from using intrathecal opioid medications.

Tools to accompany Recommendation 6:

- Dosing Guidelines
- COMM

7. Titration phase

7.1 Recommendation: Follow-up face-to-face visits should occur at least every 2-4 weeks during the titration phase.
Other guidelines with similar recommendations: 1

More frequent follow-up visits may be advisable and caution should be used when prescribing opioid medication if the patient has a known addiction problem, suspected drug-behavior problems, or co-existing psychiatric or medical problems. Frequency of visits should also be based on risk stratification (e.g., as determined by a screening tool) and the clinician's judgment (taking into account the volume of the drug being prescribed and how likely it is to be abused) [2].

7.2 Recommendation: When pain and function have not sufficiently improved on a current opioid dose, a trial of a slightly higher dose could be considered.
Other guidelines with similar recommendations: 1, 2

The rate at which the dosing is increased should balance the risk of leaving the patient in a painful state longer than necessary by going too slowly with the risk of causing harm, including fatal overdose, by going too fast. Ideally, only one drug at a time should be titrated in an opioid-naïve patient [1]. Age, health, and severity of pain should be taken into consideration when deciding on increments and rates of titration. Particular caution should be used in titrating dosing of methadone.

Evidence and other guidelines are not in agreement regarding the risks and benefits of high daily doses of opioid measured in morphine equivalents. However, it seems likely that

the risk-benefit ratio is less favorable at higher doses. Clinicians should consider consultation with a pain management specialist for patients receiving high dosages, defined as being above 120-200 mg of morphine equivalent dose per day [5].

During titration, all patients should be seen frequently until dosing requirements have stabilized. Patients should be instructed to *Use Only as Directed*, that is, not to change doses or frequency of administration without specific instructions from the clinician.

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7.3 Recommendation: During the titration phase, until the patient is clinically stable and is judged to be compliant with therapy, it is recommended that the clinician check the CSDB at least quarterly.

For more information about the CSDB, refer to Recommendation 3.3.

Tools to accompany Recommendation 7:

- Dosing Guidelines

8. Maintenance - Periodic monitoring and dose adjustments:

8.1 Recommendation: Assess each of the following four areas of concern at each visit: Analgesia, activity, adverse effects, and aberrant behavior.
Other guidelines with similar recommendations: 2, 4

These assessments can be remembered as the "four A's" (Passik & Weinreb, 2000):

- Analgesia: inquire about level of pain (current, recent, trends, etc.)
- Activity: assess both the patient's function and overall quality of life
- Adverse events: determine whether the patient is having medication side effects
- Aberrant behavior: regularly evaluate for possible drug abuse-related behavior.

A sample checklist for signs of aberrant behavior is included in the Tool Section [2].

8.2 Recommendation: Drug screening should be performed on randomly selected visits and any time aberrant behavior is suspected

Base the average frequency of random drug screening on the assessed degree of risk of aberrant behavior for the individual patient. Pill counts may be useful in some circumstances. In the case of a patient who is already supposed to be taking opioid medication, this test can also help determine whether the medication is being used as directed by the patient or being improperly diverted.

8.2 Recommendation: During maintenance phase CSDB should be checked at least annually.

After the titration phase is complete and the maintenance phase is underway, the frequency of checks of the CSDB can be based on clinical judgment, but should be no less than annually. High risk patients and patients exhibiting aberrant behavior should be checked more often. For more information about the CSDB, refer to Recommendation 3.3.

Consider evaluating for possible drug abuse-related behavior at each visit. A sample checklist is included in the Tool Section [2].

Consider additional education for patients at follow-up visits [4].

Review the pathophysiologic hypothesis (to see if the diagnosis is still valid) at each visit [4].

8.3 Recommendation: Continuation or modification of therapy should depend on the clinician's evaluation of progress towards stated treatment goals.
Other guidelines with similar recommendations: 4

These include reduction in a patient's pain scores and improved physical and/or psychosocial function.

If treatment goals are not being achieved, including patient compliance with agreed-upon activity level, despite medication adjustments, the clinician should reevaluate the appropriateness of continued treatment with the current medications [5, 6].

Frequent adjustments, after a reasonable time interval of titration, are an indication for a reevaluation of the underlying condition and consideration of the possibility the patient has developed opioid hyperalgesia, substantial tolerance, or psychological/physical dependence.

8.4 Recommendation: Adjustments to previously stable maintenance therapy may be considered if the patient develops tolerance, a new pain-producing medical condition arises or an existing one worsens, or if a new adverse effect emerges or becomes more clinically significant.
Other guidelines with similar recommendations: 1

Options for adjustment include reducing medication or rotating opioid medication. If it is documented that the patient is compliant with agreed-upon recommendation such as exercise, working, etc., addition of supplemental short-acting medications for control of break-through pain exacerbation (e.g., as related to an increase in activity, end-of-dose pain, weather-related pain exacerbation, or specific medical conditions) can be considered as well. If patients do not achieve effective pain relief with one opioid, rotation to another frequently produces greater success (Quang-Cantagrel, Wallace, & Magnuson; 2000).

Only if the patient's situation has changed permanently and consideration has been given to increased risk of adverse events, is it reasonable to consider an ongoing increase in maintenance dosing [1].

If rotating among different opioid medications, refer to a standard dosing equivalence table (See the Dosing Guidelines in the Tool Section), taking into account the current drug's half-life.

In general, if the patient's underlying medical condition is chronic and unchanging, and if opioid-associated problems (hyperalgesia, substantial tolerance, important adverse effects) have not developed, it is recommended that the effective dose achieved through titration not be lowered once the patient has reached a plateau of adequate pain relief and functional level [1].

8.5 Recommendation: Dosing changes should generally be made during a clinic visit.
Other guidelines with similar recommendations: 1

If, as with acute pain, the patient's underlying pain-producing chronic medical condition improves, it is expected that the clinician will begin tapering the patient off the opioid medication. See Recommendation 9 for guidelines on discontinuation. Tapering opioid medication with or without the goal of discontinuation may be performed as described in Recommendation 10 or as described in Strategies for Tapering and Weaning in the Tool Section.

Tools to accompany Recommendation 8:

- Checklist for Adverse Effects, Function, and Opioid Dependence
- Signs of Substance Misuse
- Pain Management Evaluation Tool
- Dosing Guidelines
- Strategies for Tapering and Weaning

9. Evaluating the treatment trial

9.1 Recommendation: Continuing opioid treatment after the treatment trial should be a deliberate decision that considers the risks and benefits of chronic opioid treatment for that patient.

9.2 Recommendation: A second opinion or consult may be useful in making the decision to continue or discontinue the opioid treatment trial.

10. Discontinuing opioid treatment

10.1 Recommendation: If opioid treatment is proving ineffective based on treatment plan goals, or if adverse effects outweigh benefits, consider tapering and discontinuing opioid treatment.
Other guidelines with similar recommendations: 5

10.2 Recommendation: Discontinuation of opioid therapy is recommended if any of the following occurs:
- *Dangerous or illegal behaviors are identified,*
- *Patient claims or exhibits a lack of effectiveness,*
- *Pain problem resolves,*
- *Patient expresses a desire to discontinue therapy, or*
- *Opioid therapy appears to be causing harm to the patient, particularly if harm exceeds benefit.*

Other guidelines with similar recommendations: 1

The decision to discontinue opioid treatment should ideally be made jointly with the patient and, if appropriate, the family/caregiver [6]. This decision should include careful consideration of the outcomes of ongoing monitoring.

10.3 Recommendation: When possible, offer to assist patients in safely discontinuing medications even if they have withdrawn from treatment or been discharged for agreement violations.
Other guidelines with similar recommendations: 1

The goal is to taper all patients off opioid medication safely. The Strategies for Tapering and Weaning tool in the Tool Section contains advice on tapering opioid medications [5]. If the patient is discharged, the clinician is obliged to offer continued monitoring for 30 days post-discharge.

Tools to accompany Recommendation 9:
- Strategies for Tapering and Weaning

Other Issues:

11. Documentation and Medical Records

11.1 Recommendation: A written treatment plan should document objectives that will be used to evaluate treatment success.
Other guidelines with similar recommendations: 1, 2, 4, 5, 6

The objectives should address pain relief, improved physical and psychosocial function, including work and exercise compliance, and should indicate if additional diagnostic tests, consultations, or treatments are planned [4]. See Recommendations 4 and 5 respectively for details on establishing treatment goals and formulation of a treatment plan.

11.2 Recommendation: Patient/family/caregiver education should be documented in the medical record.
Other guidelines with similar recommendations: 1

The patient and/or family/caregiver (as appropriate) should review and sign a copy of the opioid medication education materials they receive. See Recommendation 5.2 for more detail about patient/family/caregiver education.

11.3 Recommendation: The written prescription for opioid therapy should be written on tamper-resistant prescription paper in a manner to help reduce the likelihood of prescription fraud or misuse.
Other guidelines with similar recommendations: 2

The written prescription for opioid therapy should contain the name of the drug, the strength, the number of dosage units, (written numerically and in text), how the drug is to be taken, the full name, address, and age of the patient, the name, address, and DEA registration number of the practitioner, and the signature of the physician or other authorized practitioner. It shall be dated and signed on the day when issued. Once the maintenance therapy plateau and goals have been obtained, schedule 2 opioid medications may be prescribed for three months in advance. Each prescription for one month should include the date the prescription is written and the date listed on the prescription as to when it is to be filled.

To reduce the chance of tampering with the prescription, write legibly, and keep a copy [2]. See the Tamper Resistant Requirements in the Tool Section.

11.4 Recommendation: Assessment of treatment effectiveness should be documented in the medical record.
Other guidelines with similar recommendations: 2, 4, 5

Document the patient's progress toward treatment goals, including functional status, at every visit, rather than merely reporting the patient's subjective report of decreased pain. Ideally, this progress would be evaluated using validated tools [4].

11.5 Recommendation: The clinician should document the progress of the underlying medical condition that is causing the patient's pain.

Both the underlying medical condition responsible for the pain, if known, and other medical conditions that may affect the efficacy or risks of adverse events should be evaluated and documented at every visit.

11.6 Recommendation: Adherence to the treatment plan should be documented in the medical record.
Other guidelines with similar recommendations: 1

Specific components of the treatment plan for which adherence should be assessed include:

- Use of opioid analgesics
- Follow-up referrals, tests, and other therapies

11.7 Recommendation: Document evidence of aberrant behavior.

Clinicians are encouraged to make use of resources provided by the state of Utah that are designed to assist them in managing patients with aberrant behavior (See Checklist for Adverse Effects, Function, and Opioid Dependence and Signs of Substance Misuse in Tool Section). Referral to law enforcement/legal agencies may be appropriate if actions by patients are occurring that could be criminal in nature [1].

Consult with legal counsel prior to contacting law enforcement [1]. Serious non-adherence issues (illegal, criminal, or dangerous behaviors, including altering of prescriptions) may also warrant immediate discontinuation of opioid therapy. See Recommendation 10.

Tools to accompany Recommendation 11:

- Utah's Tamper Resistant Requirements
- Checklist for Adverse Effects, Function, and Opioid Dependence

- Signs of Substance Misuse

12. Consultation and management of complex patients

12.1 Recommendation: To achieve treatment objectives, clinicians may consider referring a patient to a specialist for additional evaluation as clinically indicated.
Other guidelines with similar recommendations: 4, 5

Prescribers may wish to consider referring patients if any of the following conditions or situations is present or if other concerns arise during treatment:

- The patient has a complex pain condition and the clinician wishes verification of diagnosis
- The patient has significant co-morbidities (including psychiatric illness)
- The patient is high-risk for aberrant behavior or addiction

The main goal of a consultation is for the prescribing clinician to receive recommendations for ongoing treatment.

12.2 Recommendation: Patients with a history of addiction or substance use disorder or who have positive drug screens indicative of a problem should be considered for referral to an addiction specialist for evaluation of recurrence risk and for assistance with treatment.
Other guidelines with similar recommendations: 1, 4, 5

Although this is a desirable approach, it is recognized that following this recommendation may not be feasible in parts of Utah where there is a shortage of readily available addiction specialists. The Directory of Resources in the Tool Section includes information on the available resources for patients such as these.

12.3 Recommendation: Pain patients who are addicted to medications/drugs should be referred to a pain management, mental health or a substance use disorder specialist if one is available, for recommendations on the treatment plan and possibly for assistance in management.

The clinician may consider prescribing opioid medication for pain even if the patient has a self-reported or documented pre-existing problem with opiates, as long as monitoring is performed during titration and maintenance phase.

12.4 Recommendation: Patients with coexisting psychiatric disorder should receiving ongoing mental health support and treatment while receiving opioid medication for pain control.

Management of patients with a coexisting psychiatric condition may require extra care, monitoring, or documentation [4, 6]. Unless the clinician treating the patient is qualified to provide the appropriate care and evaluation of the coexisting psychiatric disorder, consultation should be obtained to assist in formulating the treatment plan and establishing a plan for coordinated care of both the chronic pain and psychiatric conditions.

Tools to accompany Recommendation 12:

- Strategies for Tapering and Weaning
- Directory of Resources

13. Methadone

13.1 Recommendation: Methadone should only be prescribed by clinicians familiar with its risks and use.

Methadone-related death rates have been increasing in Utah and the U.S. In 2006, methadone was implicated in 30% of non-illicit drug-related deaths in Utah. Methadone was the most common drug identified by the Utah Medical Examiner as causing or contributing to

accidental deaths, accounting for a disproportionate number of deaths compared to its frequency of use. Methadone was the single drug most often associated with overdose death and had the highest prescription adjusted mortality rate (PAMR) with an average of 150 deaths for every 100,000 prescriptions during 1998-2004. From 1997–2004, population-adjusted methadone prescriptions increased 727%. The rise in the methadone prescription rate was for treatment of pain and not addiction therapy.

The half-life of methadone is long and unpredictable, increasing the risk of inadvertent overdose. The peak respiratory depressant effect of methadone occurs later and lasts longer after treatment initiation or dosage change than does the peak analgesic effect.

Conversion tables that have been established to assist with converting a patient from another opioid medication to methadone are considered by many experts to be unreliable.

Methadone interacts with several other medications that can alter its metabolism changing the effects of a given dose on pain and on respiratory depression. Potential for interactions should be considered before starting methadone in the presence of other medications and before starting any medication in a patient taking methadone

Methadone can prolong the QT interval and increase the risk of Torsades de Pointe, and sudden cardiac death. Caution should be used in prescribing methadone to any patient at risk for prolonged QT interval, including those with existing cardiac disease or cardiac conduction abnormalities or taking another medication associated with prolonged QT interval (Arizona Center for Education and Research on Therapeutics, 2008).

Methadone and other opioids have been associated with central sleep apnea and clinicians should consider obtaining a sleep study in patients treated with opioids, especially at higher doses, if they have developed any signs of sleep-disordered breathing or respiratory depression. In one recent case-control study, 92% of patients on opioid doses at or above 200 mg morphine equivalents had developed ataxic or irregular breathing (Walker et al, J Clin Sleep Med 2007; 3: 455-61).

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Using the Berlin Questionnaire To Identify Patients at Risk for the Sleep Apnea Syndrome

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Background: Although sleep apnea is common, it often goes undiagnosed in primary care encounters.

Objective: To test the Berlin Questionnaire as a means of identifying patients with sleep apnea.

Design: Survey followed by portable, unattended sleep studies in a subset of patients.

Setting: Five primary care sites in Cleveland, Ohio.

Patients: 744 adults (of 1008 surveyed [74%]), of whom 100 underwent sleep studies.

Measurements: Survey items addressed the presence and frequency of snoring behavior, waketime sleepiness or fatigue, and history of obesity or hypertension. Patients with persistent and frequent symptoms in any two of these three domains were considered to be at high risk for sleep apnea. Portable sleep monitoring was conducted to measure the number of respiratory events per hour in bed (respiratory disturbance index [RDI]).

Results: Questions about symptoms demonstrated internal consistency (Cronbach correlations, 0.86 to 0.92). Of the 744 respondents, 279 (37.5%) were in a high-risk group that was defined a priori. For the 100 patients who underwent sleep studies, risk grouping was useful in prediction of the RDI. For example, being in the high-risk group predicted an RDI greater than 5 with a sensitivity of 0.86, a specificity of 0.77, a positive predictive value of 0.89, and a likelihood ratio of 3.79.

Conclusion: The Berlin Questionnaire provides a means of identifying patients who are likely to have sleep apnea.

The obstructive sleep apnea–hypopnea syndrome is a potentially disabling condition characterized by excessive daytime sleepiness, disruptive snoring, repeated episodes of upper airway obstruction during sleep, and nocturnal hypoxemia. Epidemiologic surveys indicate associations among snoring, sleep apnea, and cardiovascular disease (1). A 1993 population-based study (2) of workers in Wisconsin found that 2% of women and 4% of men had symptoms of sleepiness with associated levels of sleep apnea believed to indicate at least a moderate degree of illness. Prevalence estimates from other countries and other U.S. studies are similar (3–5). Recognition of sleep apnea by community physicians is, however, low. In the Wisconsin study (6), only 7% of women and 12% of men who had moderate to severe illness reported receiving a diagnosis of sleep apnea from a medical encounter.

Two studies observed that specialist intervention with diagnostic equipment (7) or intensive physician education on taking a sleep history (8) improved recognition of sleep apnea in primary care practices. However, both approaches required substantial professional and technical resources. Asking patients to report their symptoms is a simple alternate approach that has been shown to be helpful in sleep referral clinics and community surveys (1).

The Berlin Questionnaire asks about risk factors for sleep apnea, namely snoring

behavior, waketime sleepiness or fatigue, and the presence of obesity or hypertension. We evaluated the usefulness of this instrument in identifying patients with sleep apnea in primary care settings.

See editorial comment on pp 535-536.

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Methods

The Berlin Questionnaire

The Berlin Questionnaire was an outcome of the Conference on Sleep in Primary Care, which involved 120 U.S. and German pulmonary and primary care physicians and was held in April 1996 in Berlin, Germany. Questions were selected from the literature to elicit factors or behaviors that, across studies, consistently predicted the presence of sleep-disordered breathing (1, 9–15). By consensus, the instrument focused on a limited set of known risk factors for sleep apnea. One introductory question and four follow-up questions concern snoring; three questions address daytime sleepiness, with a sub-question about sleepiness behind the wheel (that is, while driving a motor vehicle). One question concerns history of high blood pressure. Patients are also asked to provide information on age, weight, height, sex, neck circumference, and ethnicity. Obesity was quantified by calculating body mass index from self-reported weight and height. The responses to these questions have utility in non–primary care settings (1).

The conference also proposed a plan for risk grouping to simplify recognition of sleep apnea; this strategy was shown to be useful in sleep clinic and community surveys (11, 13, 15). Predetermination of high risk and lower risk for sleep apnea was based on responses in three symptom categories. In category 1, high risk was defined as persistent symptoms (□3 to 4 times/wk) in two or more questions about their snoring. In category 2, high risk was defined as persistent (□3 to 4 times/wk) waketime sleepiness, drowsy driving, or both. In category 3, high risk was defined as a history of high blood pressure or a body mass index more than 30 kg/m^2. To be considered at high risk for sleep apnea, a patient had to qualify for at least two symptom categories. Those who denied having persistent symptoms or who qualified for only one symptom category were placed in the lower risk group.

Survey Distribution

One thousand questionnaires in batches of 200 per study site were provided to individual physicians at five sites in the Cleveland, Ohio, area. The sites were chosen on the basis of geographic and socioeconomic diversity (further information is available from the authors on request). Three physicians were solo practitioners and 2 were members of a practice group; all practices were part of a hospital-owned network that at the time of study included 92 primary care physicians who cared for adults. All 5 participating physicians were Board-certified in internal medicine, and 2 had more advanced training (rheumatology or pulmonary medicine). By design, all participating physicians had practiced primary care medicine for more than 4 years and had stable practice patterns, each handling a panel of 2500 to 3000 patients. According to network records, no physician had referred more than 2 patients for sleep studies in the previous year.

Office staff handed out questionnaires to consecutive patients who visited the study physician for any reason. Each site was instructed to return the questionnaires to the sleep center. Completed questionnaires were included in our analysis if they met the following criteria: They had to be dated, the date had to fall within 3 weeks of distribution, and they had to be returned to the sleep center within 1 month. The study was approved by the institutional review board of University Hospitals of Cleveland.

Sleep Studies

Portable monitoring of respiratory disturbances during sleep was offered to both high-risk and lower-risk patients. The intent was to study approximately 20% of respondents, equally distributed in both risk groups. From an alphabetically ordered list, the first 75 patients in the high-risk group and the first 65 patients in the lower-risk group were contacted by telephone and asked to participate. Patients who agreed to sleep studies were visited at home, instructed on the use of the monitor, and monitored overnight; the monitor was retrieved the next day. Patients gave written consent for portable monitoring and for results to be sent to their primary care physician.

Monitoring was performed with a six-variable, four-channel Eden Tec recorder (Nellcor Puritan Bennett, Minneapolis, Minnesota). Variables measured included nasal and oral airflow by thermistor, chest wall movement by impedance electrodes, and oxygen

saturation (SaO_2) and pulse rate by pulse oximeter. A respiratory disturbance event was defined as a decrease in nasal or oral airflow, alone or with chest wall movement of approximately 50% that lasted for 10 seconds or more. A decrease in SaO_2 of 4% or more was considered significant oxygen desaturation. The recorder was taken to the patient's home, where he or she was instructed on how to use the recording device and to turn it on at bedtime and to turn it off upon arising (13). Measurements from a full-disclosure printout were manually scored for a respiratory disturbance index (RDI) (measured as the number of respiratory events per hour in bed) and the oxygen desaturation index (number of decreases in SaO_2 of 4% per hour in bed). Acceptable records were those in which the patients spent at least 6 hours in bed and good to excellent recording of SaO_2 and respiration (either impedance or thermistor records or both)

was achieved (13). A single researcher who had no knowledge of the questionnaire results performed the scoring.

Statistical Analysis

The quantitative distribution of returned questionnaires, individual patient variables, responses to individual questions about sleep-related symptoms, and results of home sleep monitoring are expressed by descriptive statistics (frequencies, mean SD, and range). Missing data and data that are not applicable are expressed in the percentage of the returned questionnaires and in total number of patients for each variable. Answers to questions on sex and study site were evaluated by using the chi-square test and were expressed by the significance level. The Pearson correlation test and level of significance were used to compare questionnaire responses and risk groupings. We used a logistic regression model that examined the relative effects of age, sex, and the three symptom categories and risk group. The predictive accuracy (16) of risk grouping and of each category was assessed for RDIs of 5 or less, more than 5, more than 15, and more than 30; these arbitrary cut-off values are similar to those used in previous studies (2, 6) and those proposed as diagnostic criteria (17). Computations were performed by using SPSS 7.5 for Windows (SPSS, Inc., Chicago, Illinois).

Results

Of 1008 questionnaires (one physician had distributed an additional 8 questionnaires), 744 (74%) were entered for analysis. The variability in return rate resulted from time constraints and unavailability of staff rather than patient refusal. The return rate did not correlate with the socioeconomic profile of the practice site; solo practices had greater response rates. One male respondent and one female respondent reported that they had received a diagnosis of or treatment for sleep apnea; their results were included in the analysis.

Characteristics of the respondents are shown in Table 1. Because responses to the questions on neck circumference and ethnicity were often not provided, these results were not included in the analyses.

Prevalence of Symptoms

Of the 744 respondents, 388 (52.2%) reported that they snored, 223 (30.0%) denied snoring, 118 (15.9%) did not know whether they snored, and 15 (2%) did not respond to this question. Ninety-four of all respondents (24.6%) reported that their snoring was louder than normal speech and 289 (75.4%) did not snore louder than normal speech. Two hundred three (47.9%) respondents reported snoring at least three to four times per week, and 221 (52.1%) said that they did not snore more than one to two times per week. Two hundred seventy-four (54.9%) respondents reported that their snoring bothered other people, whereas 225 (45.1%) denied that it did. In 66 (11.1%) respondents, breathing pauses during sleep were observed by others at least 1 to 2 times per month; in 31 (5.2%) respondents, breathing pauses were observed more than 3 to 4 times per week. Two hundred forty-three (33.8%) respondents stated that they did not feel rested after a night's sleep at least 3 to 4 times per week; 476 (66.2%) felt this way less often or not at all. Two hundred seventy-nine (38.8%) respondents said that they experienced waketime tiredness or fatigue at least 3 to 4 times per week; 441 (61.2%) experienced this problem one to two times per week or less often.

Of 721 (96.9% of the sample) respondents to the question about drowsiness behind the wheel, 137 (19.0%) said that they had nodded off or fallen asleep while driving. Fifteen respondents (4.4%) reported that they nodded off at the wheel at least three to four times per week. Table 2 shows the numbers of patients with these characteristics in each risk group.

Characteristic Data

Mean age SD, y 48.9 17.5
Sex, n (%) Male 310 (41.7) Female 403 (54.2) Not reported 31 (4.2)
Body mass index, n (%)
30 kg/m^2 370 (49.7)
30 kg/m^2 276 (37.1)
Not reported 98 (13.2) Mean body mass index SD, kg/m^2 29 7.2
High blood pressure, n (%)
Yes 194 (26.1) No 460 (64.7) Do not know 57 (7.7) Not reported 33 (4.4)
Mean neck circumference SD, cm† 39 4.4

* Because 632 (84.4%) of the 744 respondents did not provide information about their ethnicity, this information was excluded from analysis.
† Because 321 (43%) of the 744 respondents did not provide information about neck circumference, this information was excluded from analysis.

Internal Validity

The reliability among individual questions within symptom categories was examined as a measure of internal validity. The Cronbach □ value was 0.92 for correlation of questions within category 1 and 0.63 for category 2. When the question about sleepiness behind the wheel was excluded, the Cronbach □ value in category 2 increased to 0.86.

Table 2. Distribution of Responses by Risk Group

Patient Sex and Study Site

Men and women did not differ with respect to age (47.8 □ 16.9 years and 48.8 □ 17.8 years), body mass index (30.3 □ 6.2 kg/m^2 and 29.6 □ 7.6 kg/m^2), or history of high blood pressure (78 men [25.9%] and 109 women [28.2%]). Men were more likely than women to snore, to stop breathing during sleep, and to report drowsy driving, whereas women were more likely than men to feel tired after sleep or during waketime (data not shown).

Sites did not systematically vary for socioeconomic profile, the percentage of respondents who qualified for symptom category 1 or 2, or reports of drowsy driving (**Table 3**). Sites differed significantly for prevalence of respondents with a body mass index more than 30 kg/m^2, hypertension, or both (category 3) and for the number of respondents meeting the criteria for high risk for sleep apnea (data not shown).

The percentage of respondents in the high-risk group by study site ranged from 29% to 45%; this was not accounted for by differences in symptom categories. More men (44.5%) than women (33%) were at high risk (P □ 0.002). As expected, high-risk patients were more likely to have a higher body mass index, to be male, to have a history of high blood pressure, to have gained weight recently, to snore loudly and have observed apneas, to be tired during waketime, and to fall asleep at the wheel. The latter three behaviors are a core set of symptoms in the definition of sleep apnea (17). A logistic regression model for risk grouping identified a significant (P □ 0.001) influence of each category without a significant contribution of age or sex.

Sleep Study Results

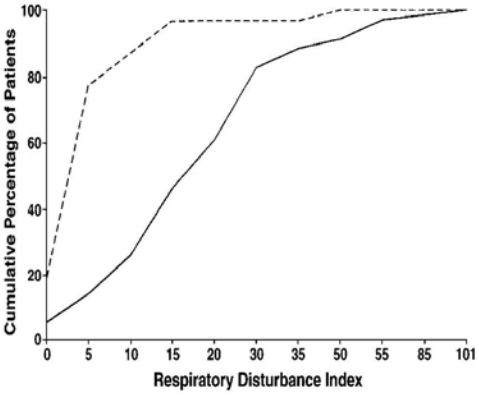
Recruitment for sleep studies and recording of data was completed for 100 (13.4%) respondents:

69 of 75 in the high-risk group and 31 of 65 in the lower-risk group. Five patients in the high-risk group and 32 in the lower-risk group declined monitoring. In 3 patients (2 at lower risk and 1 at high risk), monitoring resulted in no collected data, and these patients chose not to undergo repeated studies. Patients who underwent sleep studies did not differ significantly for age and sex between risk groups or from the total group of respondents (data not shown).

The **Figure** shows the distribution of the two risk groups with respect to RDI. The mean RDI in the high-risk group was 21.1 □ 18.5 (range, 0 to 101), the mean oxygen desaturation index was 19.4 □ 19.5 (range, 50 to 97), and the mean lowest SaO_2 was 82.6% □ 9.2% (range, 50% to 97%). Mean values in the lower-risk group were 4.7 □ 7.0 (range, 0 to 37) for RDI, 5.9 □ 7.6 (range, 0 to 35) for oxygen desaturation index, and 89.9% □ 5.9% (range, 97% to 71%) for lowest SaO_2.

Table 4 shows the ability of risk grouping to predict patients with elevated RDIs. The proportion of high-risk patients who were in the group that underwent monitoring was higher than that seen among all respondents. Nevertheless, if a patient qualifies for fewer than two risk categories—that is, if he or she is at lower risk—the likelihood that the patient has an RDI of 5 or less is strong; the corresponding post-test probability for this test result is approximately 70% (16). In contrast, high-risk patients were more likely to have an RDI of more than 5 and hence meet criteria for the obstructive sleep apnea–hypopnea syndrome (16). As the diagnostic test result threshold is increased, there is, as expected, a higher sensitivity but lower specificity.

Qualification by any one symptom category did not predict RDI thresholds as well as risk grouping did. Qualification by category 1 predicted RDI better than qualification by category 3 did, and qualification by either of these categories predicted RDI better than qualification by category 2 did (post-test probabilities, 78%, 70%, and 63%, respectively). By comparison, risk grouping resulted in a post-test probability of 85%.



Discussion

Table 3. Risk Factors and Functional Sleepiness among Study Sites*

† P □ 0.006.

* Number of respiratory events per hour in bed.

return rate (74%) was explained not by patient refusal but by the variability of interest and application by site. The Berlin Questionnaire will need to be validated in other primary care settings, and testing thresholds must be defined.

In our study, the case recognition rate for sleep apnea among primary care physicians before the survey was 0.3%, a percentage similar to previous estimates (6, 7), and participating physicians believed that sleep apnea was unusual. Although many chronic illnesses (such as diabetes) remain undetected until a sentinel event (for example, myocardial infarction) occurs, the disparity between the current detection thresholds for sleep apnea and the prevalence estimates suggested by our study and by others (6) is extraordinary. Review of the literature indicates that detection of sleep apnea remains low, even after a sentinel event, such as a car crash that resulted from falling asleep at the wheel or the development of nocturnal angina (8).

Stoohs and colleagues (18) used an extensive battery of questions administered to patients face-toface by volunteers. They estimated from symptom distributions that 20% of a primary care patient population might have sleep-disordered breathing. We used a patient-centered approach and risk grouping and found a somewhat greater prevalence. Possible explanations are

More than one third (37.5%) of outpatients who visit urban primary care physicians report risk factors (body mass index □ 30 kg/m^2 and hypertension) for and chronic behaviors (snoring, sleepiness, and tiredness) that suggest the presence of sleep disturbances and sleep apnea. A substantial proportion of these patients (4.4%) report being drowsy while driving more than three times per week. Nonetheless, primary care providers often do not ask patients about these symptoms, and sleep apnea frequently goes undiagnosed.

This report is the first to use a survey, the Berlin Questionnaire, to screen for sleep apnea in a primary care population. This approach seems acceptable to patients and may be more convenient and less costly than having the clinician screen by interview during the patient encounter. The moderate

* Patients who could not be categorized because of missing data were considered not to qualify for a particular symptom category and were therefore not included in a risk group.

‡ P □ 0.001.

Table 4. Risk Grouping and Diagnostic Test Thresholds

that our patients responded to self-reporting in a more positive manner or that symptom severity was inflated in these urban practices. The prevalence of patients at high risk in our study is higher than estimates from community-based surveys and is similar to the estimates found in surveys in cardiovascular and sleep specialty clinics (1).

The prevalence of obesity (defined in our study as a body mass index □ 30 kg/m^2) and patient-reported hypertension is similar to that found in other studies of adult primary care practices (19, 20). The links that we found between the presence of these traits and breathing disorders during sleep is not unexpected. However, reliance only on body mass index or hypertension to recognize the sleep apnea syndrome is unfounded. Many patients with a body mass index greater than 30 kg/m^2 (95 [34.4%]) or a history of high blood pressure (69 [35.6%]) in our study reported no snoring or sleepiness behavior. Furthermore, the predictive ability of the Berlin Questionnaire is higher when body mass index and high blood pressure (symptom category 3) are used in combination with snoring (symptom category 1) or sleepiness (symptom category 2) rather than alone.

Sex differences were seen in the reporting of symptoms; this finding appeared in previous studies (1). The issue has not been studied exclusively, but it may represent reporting bias or a difference in disease expression. Men reported a greater frequency of drowsy driving than did women, an observation consistent with findings from the Wisconsin cohort (21). This sex

difference did not seem to affect the validity of risk groupings because both behaviors were captured in symptom category 2.

Sleepiness is linked to a poorer general health status (22) and to car crashes (23). Of concern is that 4.4% of respondents reported that they drove while drowsy almost every day. Even if we assume that all of the persons who did not respond to the questionnaire were nondrowsy drivers, the prevalence of risk for a crash caused by falling asleep at the wheel is still high (3%). The prevalence of any report of drowsy driving was 28% among respondents in the high-risk group and was still 13% among those at lower risk for sleep apnea. Such sleepiness is an important health issue, regardless of its cause (23, 24).

Portable monitoring was used to assess the validity of the risk grouping strategy. This technique has reasonable accuracy for counting events, despite both technical and testing sources of error, compared with attended, center-based polysomnography, which also has limitations (17, 24). Risk grouping by Berlin Questionnaire responses can detect patients who meet or exceed the RDI values used in diagnostic classifications of the obstructive sleep apnea–hypopnea syndrome (17, 24). We performed a preliminary analysis of the German version of the Berlin Questionnaire in 300 patients attending pulmonary and sleep clinic specialties by comparing survey responses with results of center-based polysomnography. Our results suggested that in this specialty population, the ability of the questionnaire to predict an elevated RDI was similar to that of polysomnography (Stoohs R, Netzer N. Unpublished

data). We conclude that the Berlin Questionnaire will detect important symptom distributions and permit risk grouping in the absence of a physician– patient encounter. The sensitivity of 86% for an RDI more than 5 is higher than that of strategies currently used in clinical practice. However, physician judgment is still needed to initiate a management system, to detect unusual cases, or to recognize causes for waketime sleepiness other than sleep apnea.

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References

1 **Redline S, Strohl KP. Recognition and consequences of obstructive sleep apnea hypopnea syndrome. Clin Chest Med. 1998:19:1-19.**
2 **Young T, Palta M, Dempsey J, Skatrud J, Weber S, Badr S. The occurrence of sleep-disordered breathing among middle-aged adults. N Engl J Med. 1993;328:1230-5.**

1 **Marin JM, Gascon JM, Carrizo S, Gispert J. Prevalence of sleep apnoea syndrome in the Spanish adult population. Int J Epidemiol. 1997;26:381-6.**
2 **Olson LG, King MT, Hensley MJ, Saunders NA. A community study of snoring and sleep disordered breathing. Prevalence. Am J Respir Crit Care Med. 1995;152:711-6.**
3 **Ohayon MM, Guilleminault C, Priest RG, Caulet M. Snoring and breathing pauses during sleep: telephone interview survey of a United Kingdom population sample. BMJ. 1997;314:860-3.**
4 **Young T, Evans L, Finn L, Palta M. Estimation of the clinically diagnosed proportion of sleep apnea syndrome in middle-aged men and women. Sleep. 1997;20:705-6.**
5 **Ball EM, Simon RD Jr, Tall AA, Banks MB, Nino-Murcia G, Dement WC.**

Diagnosis and treatment of sleep apnea within the community. The Walla Walla project. Arch Intern Med. 1997;157:419-24.
8. Haponik EF, Frye AW, Richards B, Wymer A, Hinds A, Pearce K, et al.
Sleep history is neglected diagnostic information. Challenges for primary care physicians. J Gen Intern Med. 1996;11:759-61.
1 **Cirigniotta F, D'Alessandro R, Partinen M, Zucconi M, Cristina E, Gerardi R, et al. Prevalence of every night snoring and obstructive sleep apnoeas among 30-69-year-old men in Bologna, Italy. Acta Neurol Scand. 1989;79: 366-72.**
2 **Kapuniai LE, Andrew DJ, Crowell DH, Pearce JW. Identifying sleep apnea from self reports. Sleep. 1988;11:430-6.**
3 **Flemons WW, Whitelaw WA, Brant R, Remmers JE. Likelihood ratios for a sleep apnea clinical prediction rule. Am J Respir Crit Care Med. 1994;150(5 Pt 1):1279-85.**
4 **Flemons WW, Remmers JE. The diagnosis of sleep apnea: questionnaires and home studies. Sleep. 1996;19(10 Suppl):S243-7.**

13. Kump K, Whalen C, Tishler PV, Browner I, Ferrette V, Strohl KP, et al. Assessment of the validity and utility of a sleep-symptom questionnaire. Am J Respir Crit Care Med. 1994;150:735-41.
1 **Wu H, Yan-Go F. Self-reported automobile accidents involving patients with obstructive sleep apnea. Neurology. 1996;46:1254-7.**
2 **Maislin G, Pack AI, Kribbs NB, Smith PL, Schwartz AR, Kline LR, et al.**

A survey screen for prediction of apnea. Sleep. 1995;18:158-66.
1 **Sackett DL. A primer on the precision and accuracy of the clinical examination. JAMA. 1992;267:2638-44.**
2 AASM Task Force report. Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. Sleep. 1999;22:667-90.
3 **Stoohs RA, Barger K, Dement WC. Sleep disordered breathing in primary care medicine. Sleep and Breathing. 1997;2:11-22.**
4 **Kuczmarski RJ, Flegal KM, Campbell SM, Johnson CL. Increasing prevalence of overweight among US adults. The National Health and Nutrition Examination Surveys, 1960 to 1991. JAMA. 1994;272:205-11.**
5 **Logue E, Smucker ED, Bourguet CC. Identification of obesity: waistlines or weight? Nutrition, Exercise, and Obesity Research Group. J Fam Pract. 1995; 41:357-63.**

6 **Young T, Blustein J, Finn L, Palta M. Sleep-disordered breathing and motor vehicle accidents in a population based sample of employed adults. Sleep. 1997;20:608-13.**
7 **Briones B, Adams N, Strauss M, Rosenberg C, Whalen C, Carskadon M, et al. Relationship between sleepiness and general health status. Sleep. 1996;19:583-8.**
8 **Lyznicki JM, Doege TC, Davis RM, Williams MA. Sleepiness, driving, and motor vehicle crashes. Council on Scientific Affairs, American Medical Association. JAMA. 1998;279:1908-13.**
9 American Thoracic Society/American Sleep Disorders Association. Statement on health outcomes research in sleep apnea. Am J Respir Crit Care Med. 1998;157:335-41.
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I just read about this in an article in today's (01-04-2008) news paper. While I now realize that is late, I will comment anyway, as this wil highly affect me. I am a 47 year old working single mother. I have degenerative disk disease. I have been under the same doctor's care for the past 22 years, with the past 10 getting progressively worse. I have been through the spinial injections and do see a chiropractor an a regular basis. The only alternitive left is surgery to fuse my back together. Since this is a progressive disease, this means that conciveabley I could wind up having my entire back fused! What a thought! There is a new surgery on the horizon, disk replacement, however, this is still considered experitmental and is not covered by all insurance companies. Untill that day, I am not only on pain medication, I also take an antiinflamatory and a nerve medication. I am responsible about all my medications, I keep them locked in a fireproof lock box conceled in my house. I have worked for the IRS for 24 years, have a perfect driving record and no criminal record! No one knows another persons physical pain. Instead of criminalizing people who are in pain, ie random piss tests, go after the doctors who are willy nilly handing out pain scripts. DO NOT, I repeat, DO NOT go after the people who are in pain! That's an easy out with little work. Yes, I do know there is a problem, but do not punish those who are in pain and are complying with doctors and laws. Please feel free to contact me by any of the means provided, e-mail, phone or address. I am always willing to cooperate to arrive at an acceptable solution. I can tell you this, you start random drug testing and you will find yourselves bogged down with law suits and the ACLU leading the charge.

Anonymous
seems to me they had a similar bright idea about the meth use. Make it harder to get the ingrediants to produce the meth and it will reduce the meth use. I think that one bombed. Now the meth just comes from somewhere else, and the citizens go thru hell just to get cold and allergy relief.